DREAM©

Oracle Clinical™ Remote Data Capture (RDC) Onsite 4.6 User's Manual

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System Requirements

Personal Computer (PC) Requirements

In order to operate the ***Oracle Clinical Remote Data Capture (RDC) Onsite*** application, your computer must meet the following requirements:

- Windows 7.
- Internet Explorer (IE) 6 or higher.
- Adobe Acrobat Reader (or Professional) 7 or above.

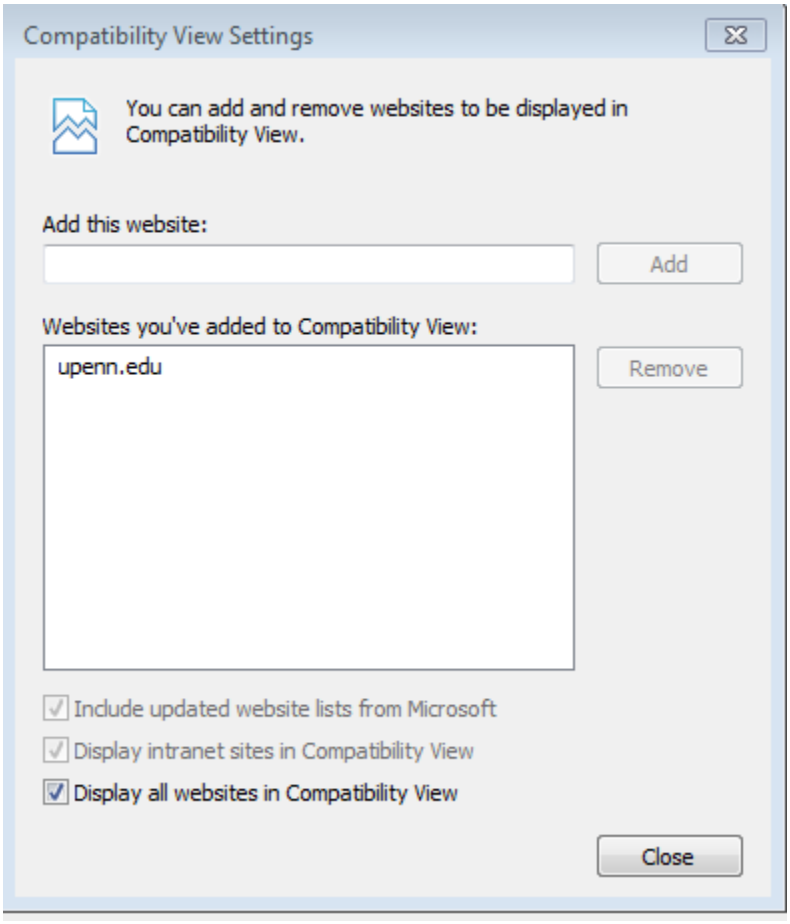
  If Adobe is not installed, it can be downloaded from the Adobe website – http://www.adobe.com. Follow the installation instructions provided on the Adobe website.
- If the Internet browser's popup blocker is enabled, make sure to allow popups from the following websites: https://crcuedc1.cceb.med.upenn.edu/.
- Disable ***Yahoo Search, Google Toolbar, AOL Toolbar, Windows Messenger*** add-ons.

  To disable then for IE 7 or above, go to the Tools menu and select Manage Add-ons; click on the add-on and check 'Disable'. Repeat for each add-on found. You need to restart IE for the changes to take effect.

Compatibility View

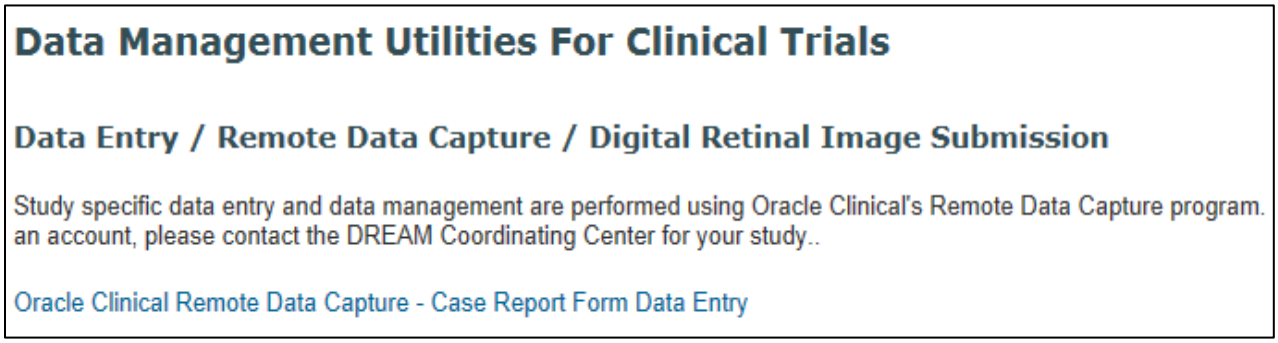
If you open a case report form in the RDC and the form appears as a blank page you will need to change the compatibility view in Internet Explorer.

To turn on compatibility view, go to the Tools Menu and choose Compatibility View settings. Make sure the “Display all websites in Compatibility View” is checked. Click on Close.


Compatibility View Settings
You can add and remove websites to be displayed in Compatibility View.
Add this website:
Add
Websites you've added to Compatibility View:
upenn.edu
Remove
Include updated website lists from Microsoft
Display intranet sites in Compatibility View
Display all websites in Compatibility View
Close

Study Landing Page

The study landing page at http://rt5.cceb.med.upenn.edu/public/dream_home.html has a convenient link to the Oracle Clinical™ Remote Data Capture (RDC) system. Be sure to bookmark this page as a favorite.


Data Management Utilities For Clinical Trials
Data Entry / Remote Data Capture / Digital Retinal Image Submission
Study specific data entry and data management are performed using Oracle Clinical's Remote Data Capture program.
an account, please contact the DREAM Coordinating Center for your study..
Oracle Clinical Remote Data Capture - Case Report Form Data Entry

Logging In

Clicking on the link Oracle Clinical Remote Data Capture – Case Report Form Data Entry will access the Login Page of the RDC.

Enter your assigned User Name and Password and click Login. The User Name and a temporary password are provided by the DREAM Coordinating Center. During the first login, you will receive a prompt to change your password.

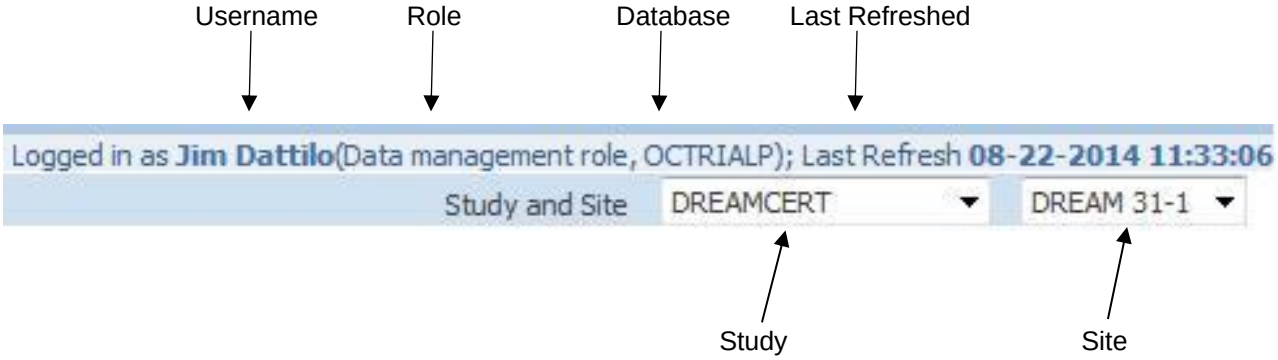
If you forget your password, you cannot log in to RDC Onsite. To request a password reset, you can contact: crcuhelp@mail.med.upenn.edu.

During certification, logging in will allow access to the DREAMCERT database. This is the database where the required exercise is entered. After certification, you will be given access to the live study database.

It is important that you keep your login information confidential. This information acts as an electronic signature, and attaches your name to any changes, updates, additions, or modifications within the Oracle Clinical system and can be tracked through the Audit Trail.

Data Management System (DMS)

RDC Onsite displays the session information in the upper right hand corner of the Home Page, under the global links. Session information will be visible on every page throughout the RDC Onsite Application:



Username: Your first and last name.

Role: Role corresponds to your username. Different roles have different levels of access and privileges within the RDC Onsite application.

Database: Displays the name of the database to which you are currently logged into.

Last Refreshed: Displays the date and time the view was last refreshed in response to any action from you, such as entering and saving data on a participant.

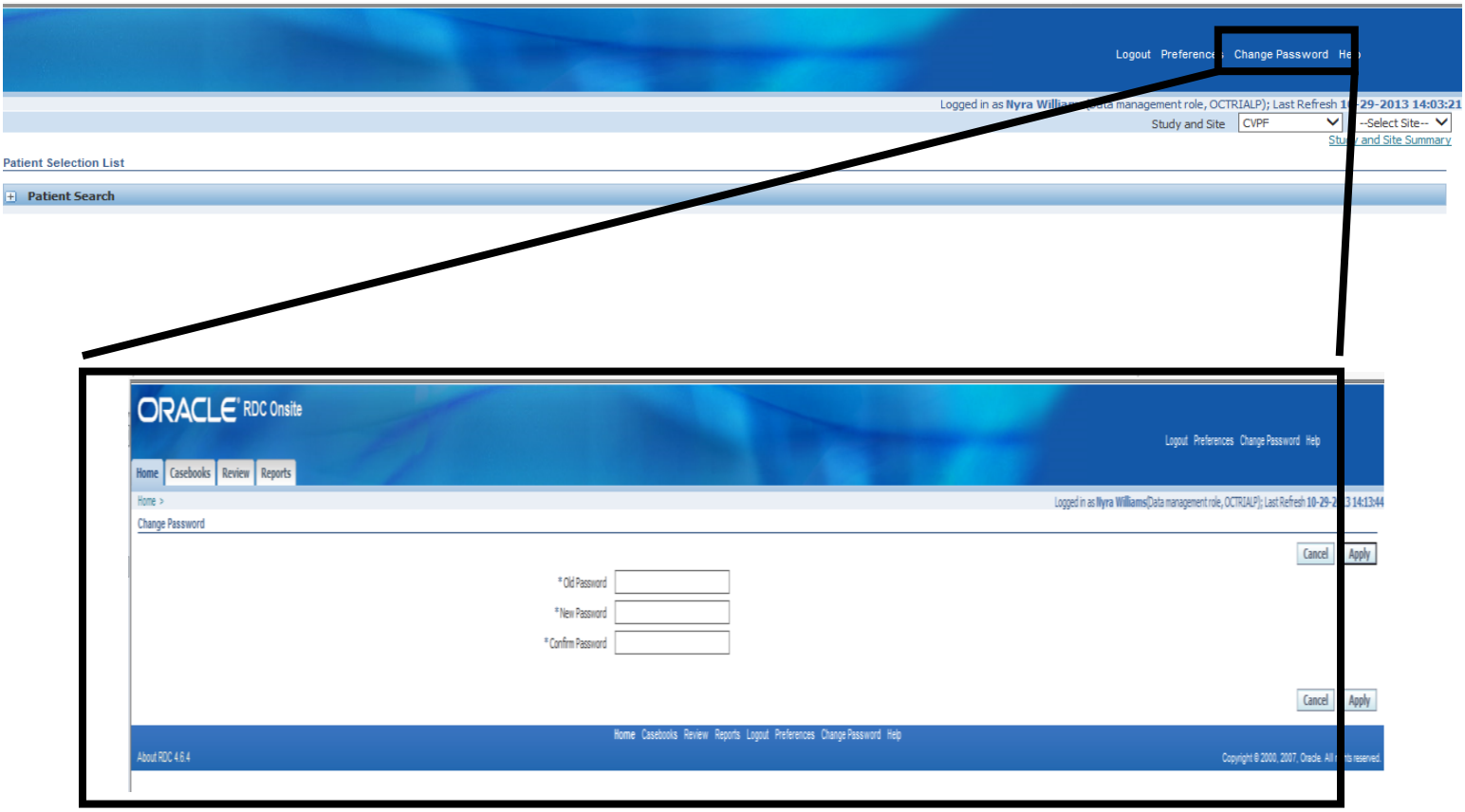
Study: The name of the Study you are currently logged into will appear here. The dropdown list allows you to select from the studies you have access to.

Site: The name of the Site currently logged into. Ability to select sites from the dropdown menu is dependent upon your account's access permissions.

Password Management

Steps to change Passwords, after logging into RDC Onsite:

1. Click ***Change Password*** in the upper right-hand corner of the header of the RDC Onsite 4.5.3 Home Page.
2. Enter the old password in the ***Old Password*** field.
3. Enter the new password in the ***New Password*** field.
4. Re-enter the new password in the ***Confirm Password*** field.
5. Click ***Apply*** to process the change.

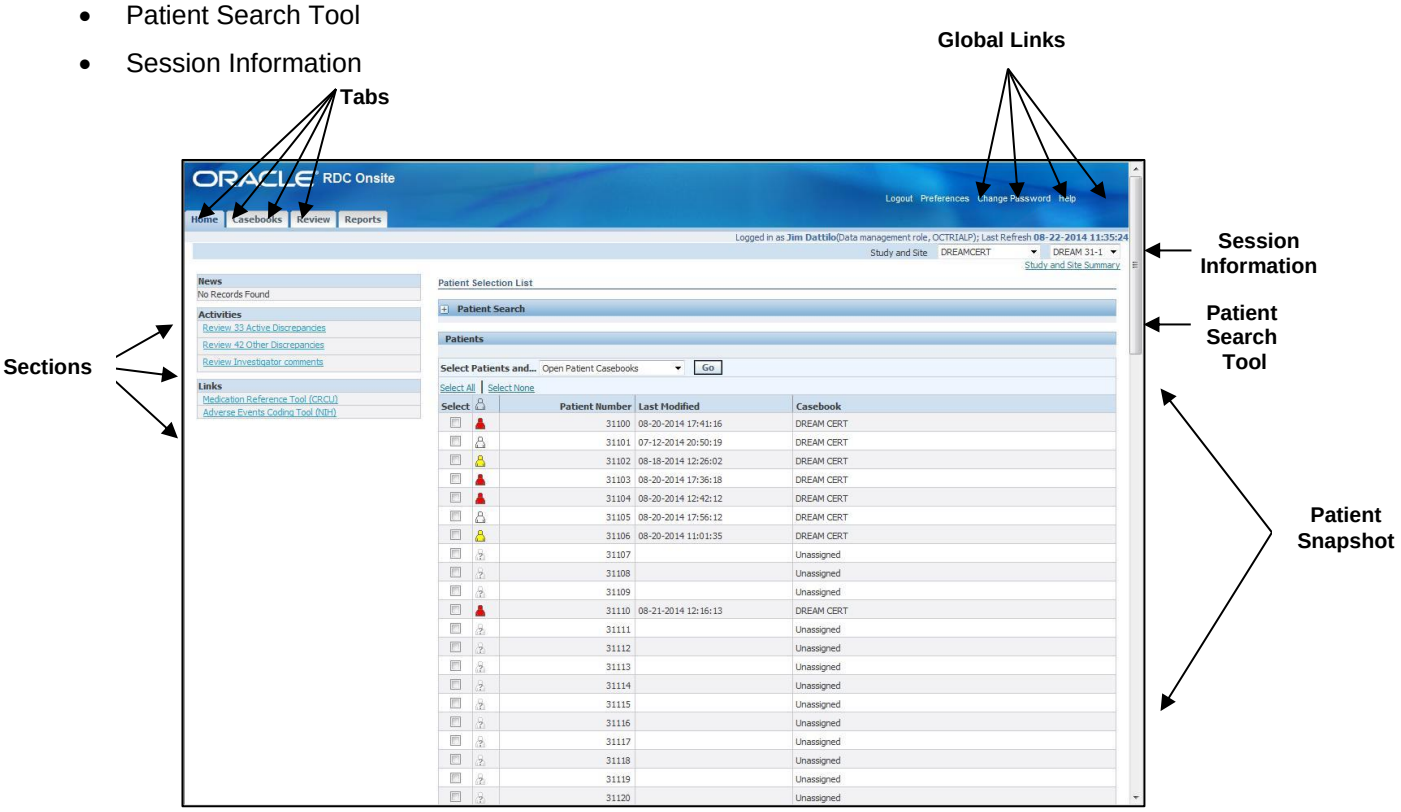


DMS Navigation and General Overview

Home Page in RDC Onsite:

Below is a snapshot of the RDC Onsite Home Page, the following features will be described in more detail throughout this section:

- Tabs
- Sections
- Global Links
- Patient Snapshot
- Patient Search Tool
- Session Information



RDC Onsite organizes and displays information in pages, oriented towards user tasks. There are two main types of pages that make up RDC Onsite:

Surround Pages: The ***Surround pages*** provide a way for you to review and interact with data. Examples of the Surround pages include: Home Page, the Casebook Page, the Review Page, and the Reports Page. All of which are accessible via the Tabs.

Data Entry Window (DEW):
The ***Data Entry Window (DEW)*** displays a Case Report Form (CRF) that you can select and open from the Casebooks and Review Surround Pages.

Home Page in Review:

Tabs act as navigational tools presented in the upper left corner (like file tabs) and are also incorporated into the global links at the bottom of each page throughout the RDC Onsite application.

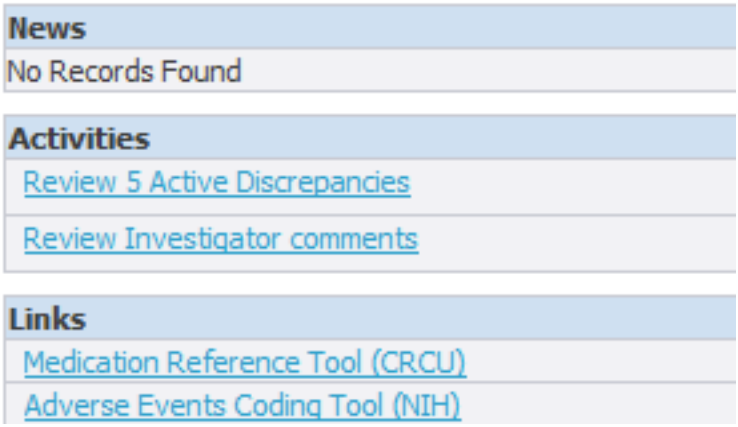
Home: Home Page appears when logged into RDC Onsite and acts as the activity page – providing News Items, Actionable Items, Snapshots, and Search functionalities.

Casebooks: Casebooks Tab allows access to the *only* page in RDC Onsite where data entry into a CRF can be initiated.

Review: Review Tab access pages from which you can review general information about CRFs, discrepancies, and investigator comments (these dialog boxes are available as sub-tabs on the Review Page).

Reports: Reports tab accesses the Reports Page – NOTE: This Feature is NOT available in the study.

Sections provide information and a snapshot of actionable items.



Activities: Provides customized tasks based on your role. The tasks are displayed as hyperlinks. Click the link Review 5 Active Discrepancies to access the ***Review Page*** and activate the ***Review Discrepancies*** page to view only those that require your attention.

Links: Reference links that are external to the RDC Onsite system. These links can be private (password protected) or public sites.

Global Links are located across the bottom (full list of links) and in the right corner (subset list of links) of each application page within RDC Onsite.

(Full List of Links – Bottom of the Screen)

Home: Access to the Home Page within RDC Onsite.

Casebooks: Access to the Casebooks Page and allow data entry within RDC Onsite.

Review: Access to the Review Page within RDC Onsite.

Reports: Access to the Reports Page within RDC Onsite (Not available in this study).

Logout: Logout of RDC Onsite. The Home Page Session view will display the site and study last visited.

IMPORTANT: For Security, use the ***LOGOUT*** *t*o securely end a given session. Do not close or "X" out of a window and assume you have been successfully logged out of the application.

Preferences: Change the way RDC Onsite displays data.

Number of News items, Activities, and Links to display:
Specify the maximum number of items to be displayed in the News, Activities, and Links section of the Home Page. If the number of items exceeds the maximum display limit specified here, RDC Onsite will add **NEXT** and **Previous** links within the section boxes.

Number of items to display, all other lists (except on Patient Casebooks page):
Specify the maximum number of patients, CRFs, discrepancies, and investigator comments to be displayed at a time on the Home Page and Review Page within RDC Onsite.

Input Date Format: Change the way the date is recorded during data entry. The formats are: US (mm-dd-yyyy), European (dd-mm-yyyy), and Swedish (yyyy-mm-dd). The ***STANDARD OPTION*** is US format (mm-dd-yyyy).

Display date format: Change the way the date gets displayed throughout the RDC Onsite application. The formats are the same as described above.

Display time stamps in local time zone:
Display timestamps in the local time zone. This will only affect audit trail information displayed, such as Last Modified, when looking at discrepancy information in the review tab.

APPLY to save any changes entered; ***CANCEL*** to return to the previous page.

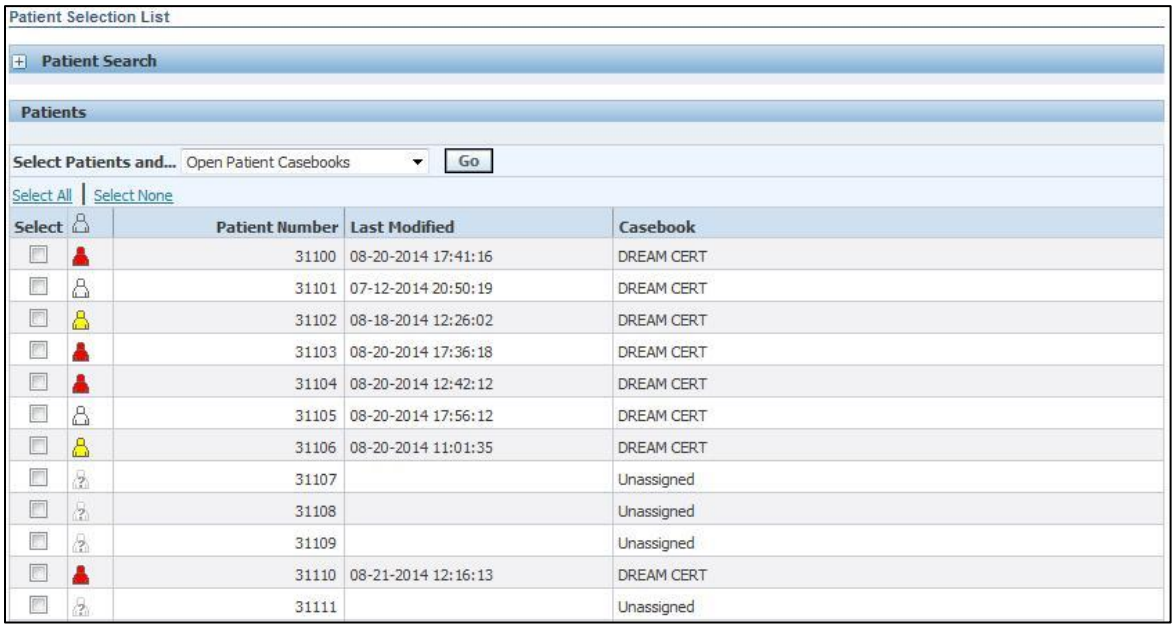
Change Password: will allow the user to change their password, as described in the Logging-In section.

Contact us:	will allow the user to email technical questions or issues directly to the Help Desk: crcuhelp@mail.med.upenn.edu.
Help:	will allow the user to open a web based help dictionary on a variety of RDC Onsite related topics.

Participant Selection

Patient Snapshot or Patient Selection List is located on the Home Page and lists a snapshot of patients for the site.

The Patient Snapshot consists of two components – ***Patient Search and Patients:***



Select	Patient Number	Last Modified	Casebook
	31100	08-20-2014 17:41:16	DREAM CERT
	31101	07-12-2014 20:50:19	DREAM CERT
	31102	08-18-2014 12:26:02	DREAM CERT
	31103	08-20-2014 17:36:18	DREAM CERT
	31104	08-20-2014 12:42:12	DREAM CERT
	31105	08-20-2014 17:56:12	DREAM CERT
	31106	08-20-2014 11:01:35	DREAM CERT
	31107		Unassigned
	31108		Unassigned
	31109		Unassigned
	31110	08-21-2014 12:16:13	DREAM CERT
	31111		Unassigned

Patient Search: Displays a subset of patients.

Range: Search a range of patient numbers in terms of FROM and TO. Click on the magnifying glass icon to select values from the patient identifier list and also to define a range. Blank patient Range fields indicate that all patients should be displayed. Only entering one number in either the FROM or TO will return only that patient number.

Assigned Book: The name of the patient casebook.

Show: View three possible "sets" or groups of patients:

All – all patients are shown. This is the Default view.

Patients with data entered – select this view to review data already entered. On the Home Page and Casebook Page selecting this option will eliminate patient rows from view for those patients who have no saved data.

Patients with no data entered – select this view when initiating data entry for new patients. This view will only show patients who have no data entered and are available for data entry.

Discrepancy Status:

View patients with discrepancies. From the Home Page view the results appear as patient-level discrepancies (patients with discrepancies); other pages within the RDC Onsite application display results CRF-level discrepancies. ***The discrepancy statuses are:***

All – all patients regardless of their discrepancy status are displayed. This is the default value.

Active – display only patients with active discrepancies. These discrepancies are based on logic checks, range checks, and other study defined criteria per CRF.

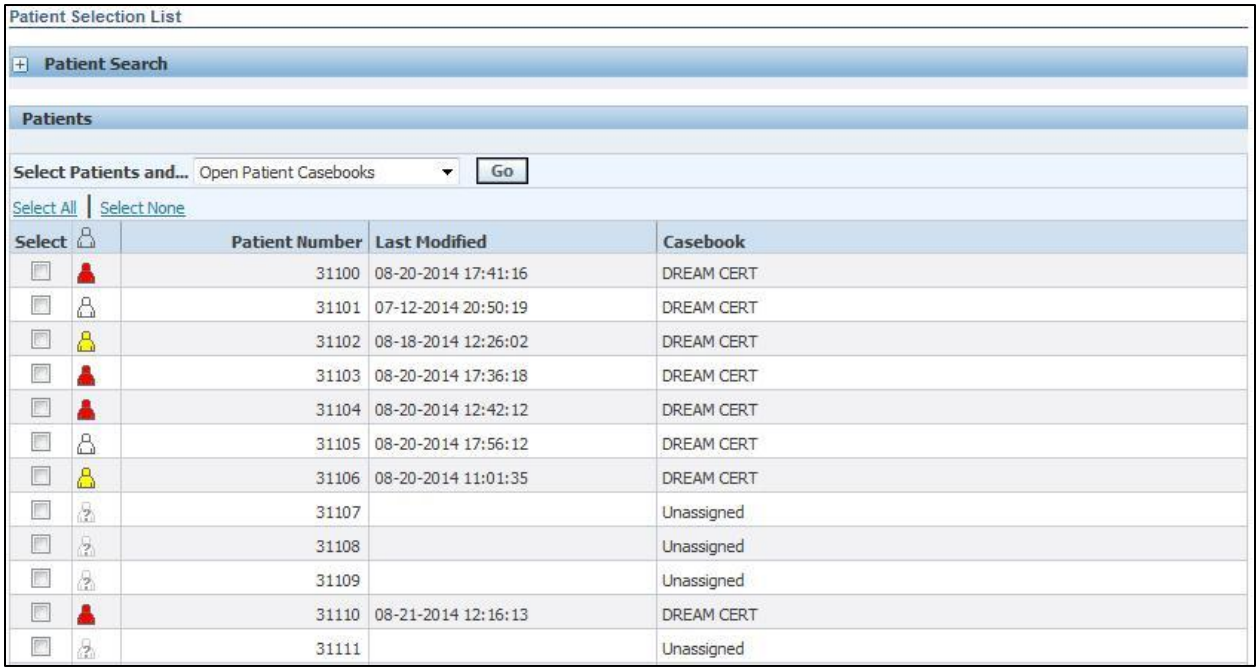
Other – display only patients with other discrepancies. These are eligibility discrepancies during the screening and baseline visits.

Open (Active & Other) – display open discrepancies that are active and other.

Clean (None or Closed) – retrieve patients with no open (active or other) discrepancies.

Patients: Provides brief information about each patient depending upon the search criteria selected.

The description below refers to patients for a site that have had no search criteria entered.



Select	Patient Number	Last Modified	Casebook
	31100	08-20-2014 17:41:16	DREAM CERT
	31101	07-12-2014 20:50:19	DREAM CERT
	31102	08-18-2014 12:26:02	DREAM CERT
	31103	08-20-2014 17:36:18	DREAM CERT
	31104	08-20-2014 12:42:12	DREAM CERT
	31105	08-20-2014 17:56:12	DREAM CERT
	31106	08-20-2014 11:01:35	DREAM CERT
	31107		Unassigned
	31108		Unassigned
	31109		Unassigned
	31110	08-21-2014 12:16:13	DREAM CERT
	31111		Unassigned

Select: Select patient by checking the box in the first column.
In "Select Patients and…", select an action to execute on the patients from the dropdown menu:

Open Patient Casebooks – open the casebooks for the selected patients.

Review Discrepancies – review open discrepancies for the selected patients.

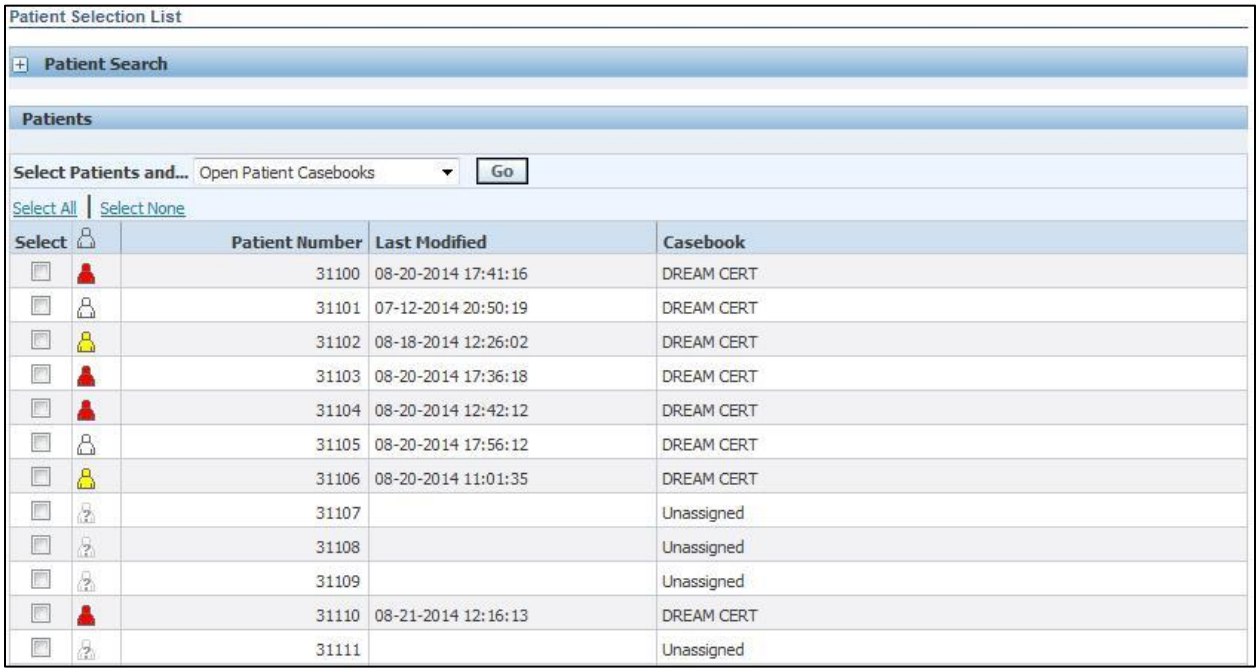
Review Entered CRFs – review entered CRFs for the selected patients.

Review Investigator Comments – review investigator comments for the selected patients.

Generate Patient Data Report – This feature is not available in this study.

Generate Blank Casebook Report –This feature is not available for this study. Blank case report forms are available on the DREAM landing page.

Review MedDRA Dictionary / AE – review the coded Adverse Event information for the selected patients. This feature is not used for most studies.



Select	Patient Number	Last Modified	Casebook
	31100	08-20-2014 17:41:16	DREAM CERT
	31101	07-12-2014 20:50:19	DREAM CERT
	31102	08-18-2014 12:26:02	DREAM CERT
	31103	08-20-2014 17:36:18	DREAM CERT
	31104	08-20-2014 12:42:12	DREAM CERT
	31105	08-20-2014 17:56:12	DREAM CERT
	31106	08-20-2014 11:01:35	DREAM CERT
	31107		Unassigned
	31108		Unassigned
	31109		Unassigned
	31110	08-21-2014 12:16:13	DREAM CERT
	31111		Unassigned

Patient Icons: The patient icon is represented by an anthropomorphic (human looking) figure. The color of the icon signifies the discrepancy status or entry status of a given patient. See table below:

Icon	Color	Description
	White	Patient data contains no open discrepancies.
	Gray with a question mark	No data have been entered for this patient.
	Yellow	Patient data includes discrepancies involving eligibility criteria, which requires your attention.
	Red	Patient data includes discrepancies involving non-eligibility criteria, which requires your attention.

Patient Number: The patient number or patient identification number (PID) is an assigned unique number for each patient, unique to a given site.

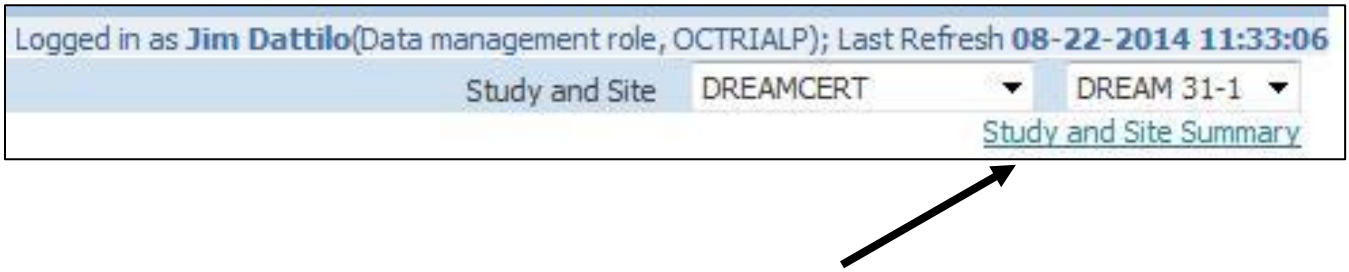
Last Modified: The value in this field represents the date and time of the last modification to the patient's entered data. A modification can represent any of the following actions: data updates, discrepancy resolution, or initial entry of a CRF.

Casebook Name: The casebook name is the name of the casebook (or CRF packet) to which a given PID has been assigned.

Provisional – casebook is currently being developed, enhancements are being made, or testing is being performed. Data entered into a provisional casebook is committed into a study database, but can be removed prior to activation.

Active – casebook is currently active or live. Data entered into an active casebook will be committed to the study database; any subsequent changes to data will be tracked via the audit trail.

Site and Study Summary is shown below the Session information on the Home Page:

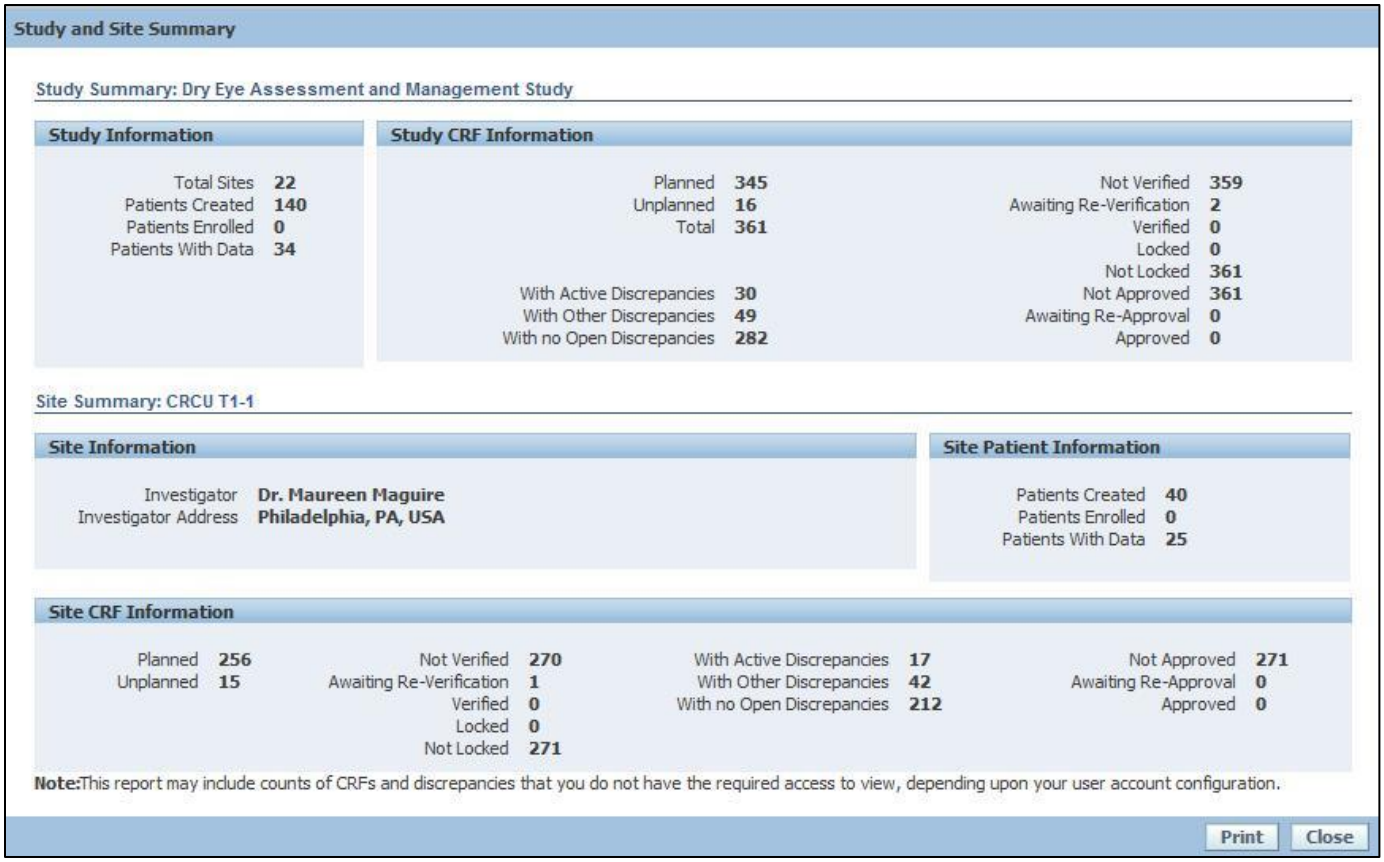

Logged in as Jim Dattilo(Data management role, OCTRIALP); Last Refresh 08-22-2014 11:33:06
Study and Site
DREAMCERT
DREAM 31-1
Study and Site Summary

To view Study and Site Summary information, click on the Study and Site Summary hyperlink below the Session information from any of the ***Surround Pages***.

Study and Site Summary information will give a snapshot of data related to:

Study Summary: provides number of sites, number of patients with data, number of CRFs, and number of discrepancies.

Site Summary: provides the name of the Investigator, address of the Investigator, patient summary information, number of CRFs with discrepancies, and number of discrepancy free CRFs.



General terminology from the display above:

Patients Created: indicates the number of patient numbers that have been pre-programmed for the study and for the site.

Patients with Data: represents the number of created patients that have at least one CRF entered and saved in the system.

Planned CRFs: the number of CRFs that have been allotted or planned per visit per patient.

Unplanned CRFs: represents the number of CRFs that were entered as unplanned forms per the existing study matrix (missed visit or telephone visit).

With Active Discrepancies: represents the number of CRFs that have open discrepancies.

> ***TIP*** – CRF level discrepancies only count forms with errors, this summary report does not represent question level discrepancies within the CRF. *Example*: if a CRF has 5 open discrepancies on the individual questions within the CRF, the statistic will be displayed in this summary view as 1 CRF with discrepancies.

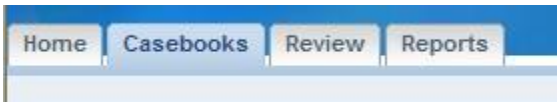
With Other Discrepancies:
represents the number of CRFs that have open discrepancies related to eligibility criteria

With no Open Discrepancies:
represents the number of CRFs without any currently open discrepancies.

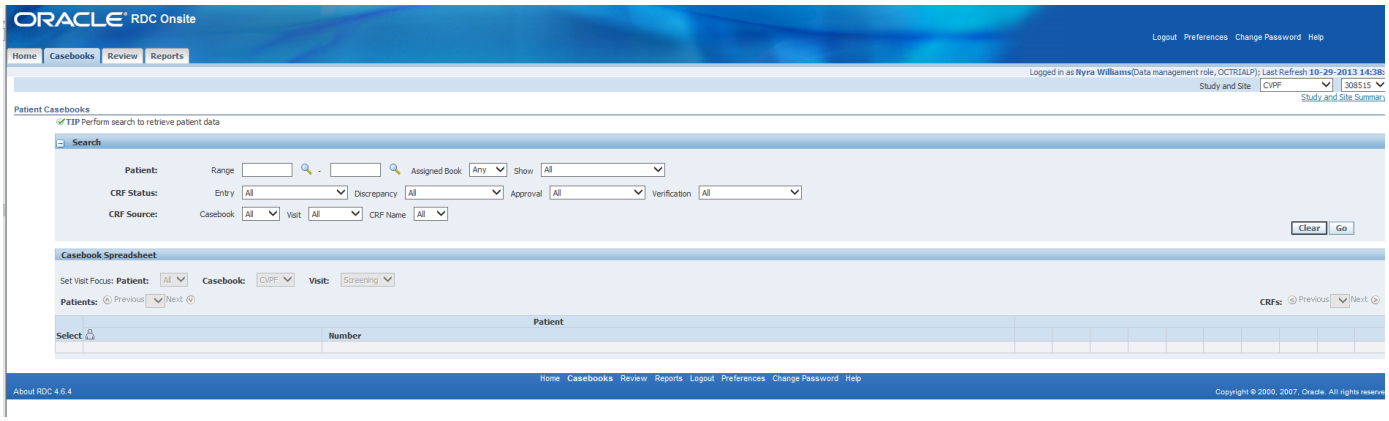
General Data Entry Instructions

Data Entry within RDC Onsite is performed from the Casebook Page. It is the only page in the RDC Onsite application where you can initiate data entry for a CRF.

Casebook Page Data Entry

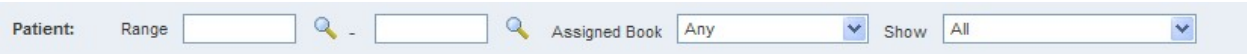


1. Click on the ***Casebooks*** tab to open the study Patient Casebooks Search and Casebook Spreadsheet display view:



2. To view patients data in the ***Casebook Spreadsheet***, either enter ***search*** parameters or click on "***Go***" in the ***Search*** section of the Casebook Page.

The features of this Search section are similar to the Search section on the Home Page.



The Search options of the ***Patient*** row:

Range: Search a range of patient numbers in terms of FROM and TO.
Click the magnifying glass icon to select values from the patient identifier list and also to define a range. Blank patient Range fields indicate that all patients should be displayed. Only entering one number in either the FROM or TO will return only that patient number.

Assigned Book: The name of the patient casebook.

Show: View three possible "sets" or groups of patients:

All – all patients are shown. This is the Default view.

Patients with data entered – select this view to review data already entered. On the Home Page and Casebook Page selecting this option will eliminate patient rows from view for those patients who have no saved data.

Patients with no data entered – select this view when initiating data entry for new patients. This view will only show patients who have no data entered and are available for data entry.

The search options of the ***CRF Status*** row:

Entry Status: Select the entry status of CRFs for the study. Each of these entry statuses have a corresponding ICON that is displayed in the Casebook Spreadsheet:

Icon	CRF Label	Description
	Placeholder	No information has been entered.
	Created	The CRF contains header field information, but no response data have been entered.
	Entry Started	The CRF contains header field information and at least some response data but has been saved incomplete.
	Entry Complete	All required CRF header and response data have been entered. The CRF has been saved complete.

Discrepancy Status: View CRFs with discrepancies.
From the Casebook Page view the results appear as CRF-level discrepancies.
The discrepancy status ICONS are:

Icon	Color	Description
	White	Patient data contains no open discrepancies.
	Yellow	Patient data includes discrepancies involving eligibility criteria, which requires your review.
	Red	Patient data includes discrepancies involving non-eligibility criteria, which requires your review.

Approval Status: View CRF Approval Status for those CRFs that require Principal Investigator (PI) approval of some aspect of data collected on a given CRF or set of CRFs.
The Approval ICONS are:

Icon	Label	Description
	None	The CRF has not been approved.
	Approved	The CRF has been approved.
	Re-approval Required	At least one data point in the approved CRF has been modified since approval. The CRF must be re-approved.

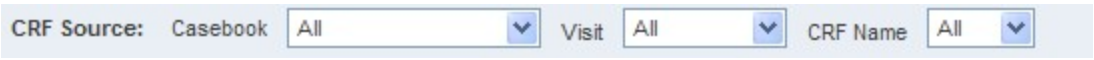
TIP: This study does not currently have any study specified elements that require electronic approval and this feature of the Search section will not return any associated data. Keep Approval Status set to the default of **ALL** or use **NONE** when searching CRF Status.

Verification Status: View CRF Verification Status for those CRFs that require the Coordinating Center Study Monitor verification of some aspect of data collected on a given CRF or set of CRFs.

The Verification Status ICONS are:

Icon	Label	Description
	None	The CRF has not been verified.
	Verified	The CRF has been verified.
	Re-verification Required	At least one data point in the verified CRF has been modified since verification. The CRF must be re-verified.

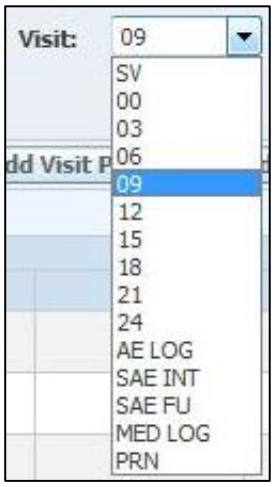
TIP: This study does not currently have any study specified elements that require additional verification and this feature of the Search section will not return any associated data. Keep Verification Status set to the default of **ALL** or use **NONE** when searching CRF Status.



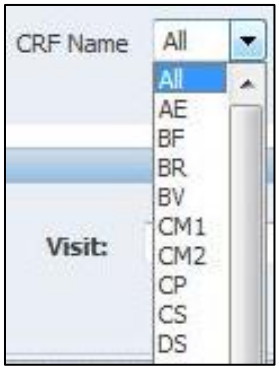
The Search options for the ***CRF Source*** row:

Casebook: will allow users to specify ALL or the study to which they are currently logged in to. From the above, users can select:

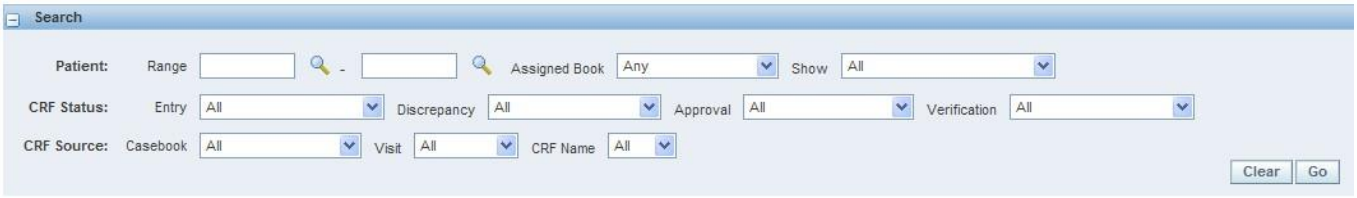
Visit: will allow users to select a specific visit name that will display CRF data in the Casebook Spreadsheet. See below for an example, users can select:



CRF Name: will allow users to select a given CRF. CRF Names can be found in the lower right-hand corner of the paper CRFs used for data collection. Below is an example of the CRF choices:

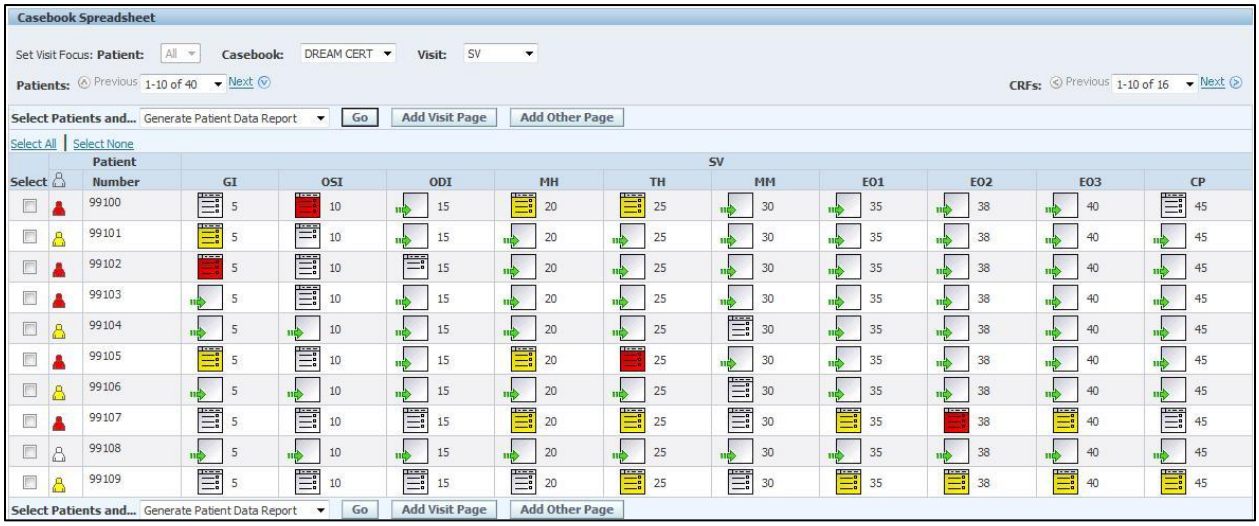


TIP: When logged into the study, users will be presented with a specific list of study CRFs.



In the above example, the Casebook Search is set to default.

1. Click "Go" to run the patient search with the default parameters. All patient CRFs will be returned (example below).



The above view shows:

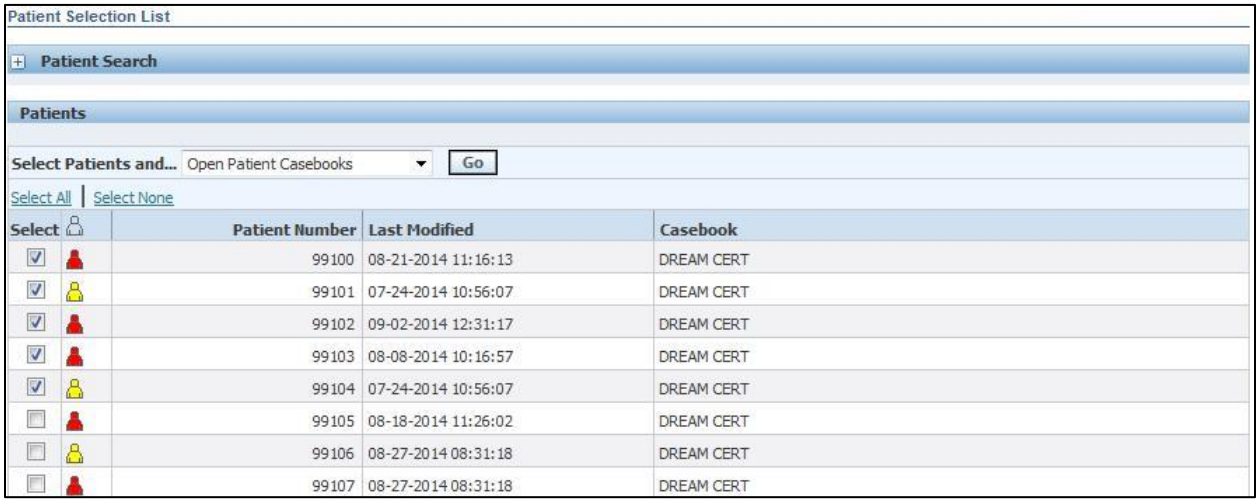
Discrepancies: There is a CRF ICON displayed in the list above. CRF level information is displayed in the Casebook Spreadsheet, which means the red CRF ICON could represent a single discrepancy or multiple discrepancies. For Patient level information, detailing how many open discrepancies per CRF, users would need to Search via the Review Tab. More information can be found in the Discrepancy Management Section of this manual.

Entered: There are CRF ICONs displayed in the list above. Users could enter these CRFs if updates or additions to the previously saved data need to be performed.

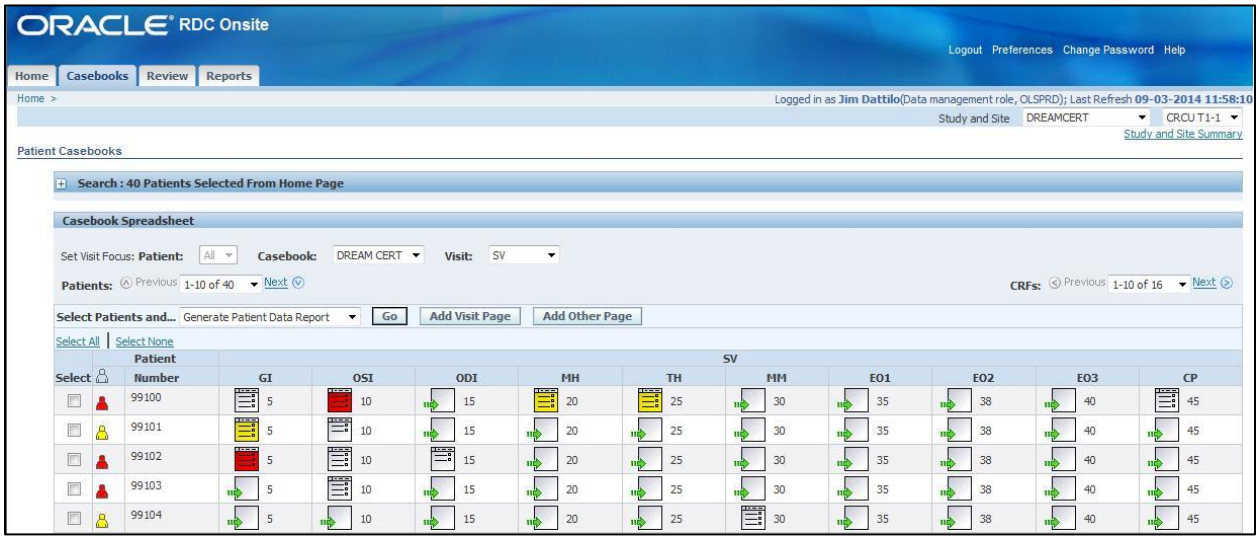
Placeholder: There are CRF ICONs displayed in the list above for available patient identification numbers. There has been no data entered or saved for these CRFs.

Home Page Selection and Casebook data entry

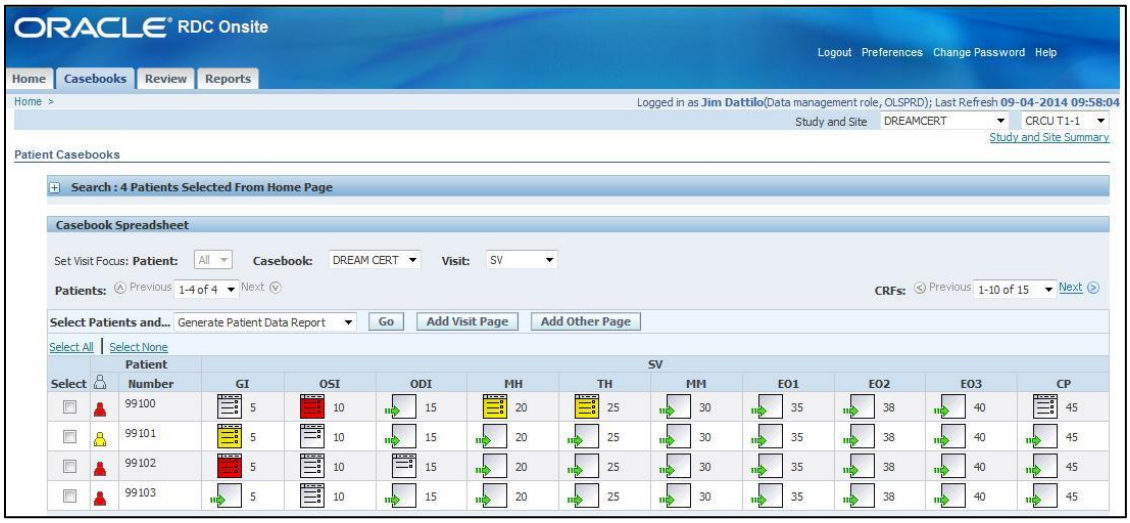
From the Home Page, you can select a set of patients from the ***Patient Snapshot*** or ***Patient Selection List*** section:



1. ***Select*** the set of patients you'd like to perform data entry for – these can be either patients with current data (continuing data entry) or patients with no data entered (new patient data entry).
2. From the ***Drop Down box,*** choose the "Open Patient Casebooks" option.
3. ***Click*** on the "***Go***" button to be taken to the Casebook spreadsheet for the selected patients.


ORACLE RDC Onsite
Logout Preferences Change Password Help
Home Casebooks Review Reports
Patient Casebooks
Search : 40 Patients Selected From Home Page
Casebook Spreadsheet
Select Patients and... Generate Patient Data Report
Go
Add Visit Page
Add Other Page
Select All | Select None
Patient Number
SV
GI OSI ODI MH TH MM EO1 EO2 EO3 CP
99100 99101 99102 99103 99104

Casebook Spreadsheet overview:


ORACLE RDC Onsite
Logout Preferences Change Password Help
Home Casebooks Review Reports
Home >
Logged in as Jim Dattilo(Data management role, OLSPRD); Last Refresh 09-04-2014 09:58:04
Study and Site DREAMCERT CRCU T1-1
Study and Site Summary
Patient Casebooks
Search : 4 Patients Selected From Home Page
Casebook Spreadsheet
Set Visit Focus: Patient: All Casebook: DREAM CERT Visit: SV
Patients: Previous 1-4 of 4 Next
CRFs: Previous 1-10 of 15 Next
Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page
Select All | Select None
Select Patient Number GI OSI ODI MH TH MM EO1 EO2 EO3 CP
99100 5 10 15 20 25 30 35 38 40 45
99101 5 10 15 20 25 30 35 38 40 45
99102 5 10 15 20 25 30 35 38 40 45
99103 5 10 15 20 25 30 35 38 40 45

- Casebook Spreadsheets displays patients in rows and the expected, study-related CRFs in columns.
- You can navigate across patients (up and down) and across visit specific CRFs (left to right).

Casebook Spreadsheet controls:

To assist in navigating in the Casebook Spreadsheet, you can make use of the controls located in the top section.

Casebook Spreadsheet
Set Visit Focus: Patient: All Casebook: DREAM CERT Visit: SV
Patients: Previous 1-4 of 4 Next
CRFs: Previous 1-10 of 15 Next

The controls, from left to right, are:

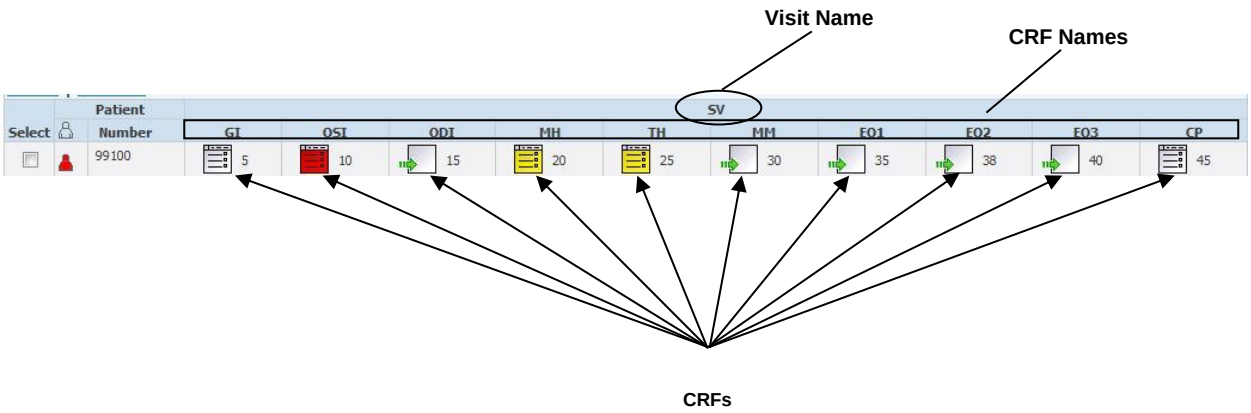
Patients: if the list of patients cannot fully be displayed, use the up and down caret signs, **Previous**, and **Next** options located in the upper left of the Casebook Spreadsheet to navigate across the groups of patients.

Casebook View: is the default Casebook or study a user is currently working in.

Visit: allows the user to select a visit from the dropdown list to view the CRFs associated with the Visit.

CRFs: if the number of columns viewable on screen is insufficient to show all CRFs for the visit selected, use (**<**) **Previous** or **Next** (**>**) in the upper right of the Casebook Spreadsheet, to navigate to visit CRFs that cannot be displayed in the current view.

Navigating within the Casebook Spreadsheet:



The information listed in the control section of the ***Casebook Spreadsheet*** corresponds to the spreadsheet view:

Visit Name: displays the current Visit Name. In the above example, **SV** is displayed.

CRF Names: the CRFs associated with the Visit are displayed under the Visit Name.

CRFs: the CRFs for the patient row are displayed with their appropriate icon. The CRFs can represent Empty CRFs or Entered CRFs.

- Clicking on one of the CRF icons will allow you to perform data entry on the CRFs for a given patient.
- The numbers beside the CRF icons act as sequence numbers for ordering and displaying the CRFs within a Casebook.

Data Entry Window (DEW)

- In RDC Onsite, the Data Entry Window (DEW) opens a pop-up window from the Casebook Surround Page.
- Users can have up to three DEWs open at a time, which operate independently of the Casebook Surround Page.

  The pop-up windows have the following functionality:

  - ***Ability to navigate between the RDC Onsite application tabs while the DEW windows are open.***

    This gives users the ability to access other areas of the application while the DEW is running without worrying about losing data or not having the ability to continue performing data entry while browsing the application.

  - ***All pop-up windows opened will remain active until the window is closed.***

    Each of these pop-up windows will display a unique name displayed in the Internet Window Header and also in the Windows Taskbar at the bottom of the screen:

RDC Onsite: Patient Casebooks - Windows Internet Explorer provided by Comcast
RDC Onsite DE: 100002, BASELINE, DEMO - Windows Internet Explorer provided by Co...
http://rt7.cceb.upenn.edu/olsa/oc/rdcOpenHtmlCrf.do?vobj=RdcMPCasebookCrfDetailsVO1&ppid=68917615&rdciid=19585
ORACLE RDC Onsite: Data Entry
RDC Onsite DE: 100003, BASELINE, DEMO - Windows Internet Explorer provided by Co...
http://rt7.cceb.upenn.edu/olsa/oc/rdcOpenHtmlCrf.do?vobj=RdcMPCasebookCrfDetailsVO1&ppid=68917715&rdciid=0&crfr
ORACLE RDC Onsite: Data Entry

In the example above the farthest window is the Casebook Surround Page, the middle window is the Baseline DEMO form for patient 100002, and the closest window is the Baseline DEMO form for patient 100003.

Opening a Data Entry Window (DEW):

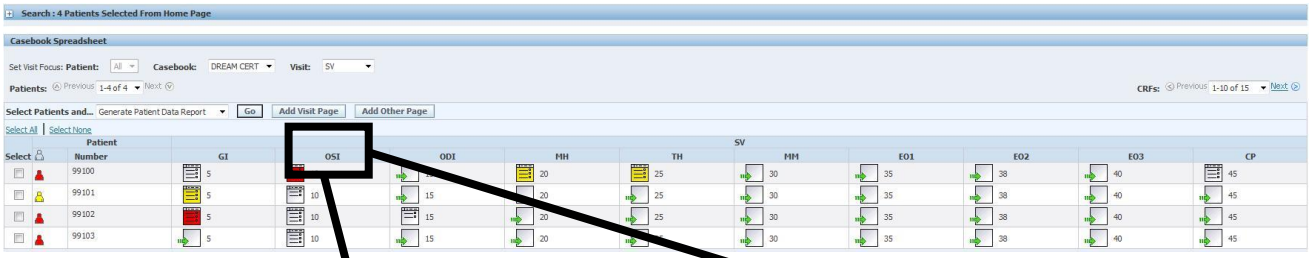
1. Click on a CRF icon from either the ***Casebook Page*** or the ***Review Page***.

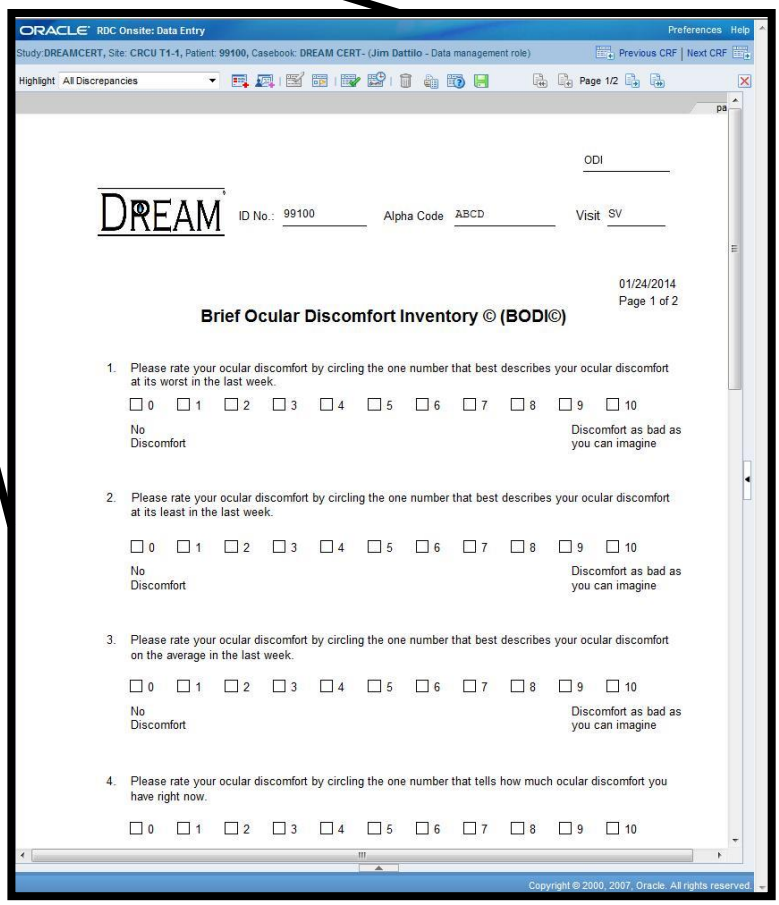
Placeholder or ***Empty CRF***:

The Casebook Spreadsheet is the only section of RDC Onsite that displays empty CRF icons. These icons symbolize a CRF that is empty and awaiting data entry.

2. Click an empty CRF icon in the Casebook Spreadsheet to open the pop-up DEW and begin data entry.

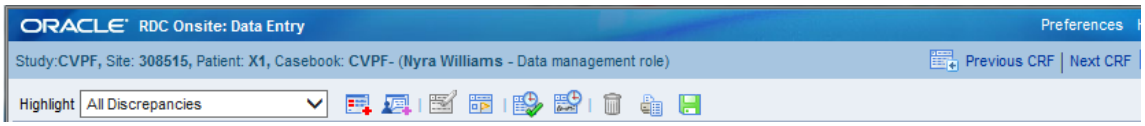
Entered CRFs: Entered CRFs contain data and can be accessed from either the ***Casebook Page*** or the ***Review Page*** and opened in a DEW to update data.




ORACLE RDC Onsite: Data Entry
Preferences Help
Study:DREAMCERT, Site: CRCU T1-1, Patient: 99100, Casebook: DREAM CERT- (Jim Dattilo - Data management role)
Previous CRF | Next CRF
Highlight All Discrepancies
Page 1/2
ODI
DREAM
ID No.: 99100
Alpha Code ABCD
Visit SV
01/24/2014
Page 1 of 2
Brief Ocular Discomfort Inventory © (BODI©)
1. Please rate your ocular discomfort by circling the one number that best describes your ocular discomfort at its worst in the last week.
0 1 2 3 4 5 6 7 8 9 10
No Discomfort
Discomfort as bad as you can imagine
2. Please rate your ocular discomfort by circling the one number that best describes your ocular discomfort at its least in the last week.
0 1 2 3 4 5 6 7 8 9 10
No Discomfort
Discomfort as bad as you can imagine
3. Please rate your ocular discomfort by circling the one number that best describes your ocular discomfort on the average in the last week.
0 1 2 3 4 5 6 7 8 9 10
No Discomfort
Discomfort as bad as you can imagine
4. Please rate your ocular discomfort by circling the one number that tells how much ocular discomfort you have right now.
0 1 2 3 4 5 6 7 8 9 10
Copyright © 2000, 2007, Oracle. All rights reserved.

Data Entry Window (DEW) toolbar:

DEWs have a standard toolbar to facilitate work within the CRF:


ORACLE RDC Onsite: Data Entry
Preferences
Study:CVPF, Site: 308515, Patient: X1, Casebook: CVPF- (Nyra Williams - Data management role)
Previous CRF | Next CRF
Highlight
All Discrepancies

The DEW toolbar icons are described below:

Icon	Description	Function
	Add Discrepancy	The Add Discrepancy window opens.
	Investigator Comment	The Add/Update Investigator Comment window opens.
	Delete Row	The Delete Row dialog opens.
	Blank Flag Tool	The CRF Blank Selection(s) Processing dialog opens.
	Verification History	The Verify CRF window opens.
	Approval History	The Approve CRF window opens.
	Delete CRF	The Delete CRF window opens.
	Print	The Print options for the local user open.
	CRF Help	The optional CRF Help provided by your sponsor, opens.
	Save	RDC Onsite saves the CRF and displays a confirmation message.
	Previous CRF	Navigate to the previous CRF. This link appears only if a CRF is opened from the Casebooks Page. The link is disabled in the first CRF in a visit for a patient.
	Next CRF	Navigate to the next CRF. This link appears only if a CRF is opened from the Casebooks Page. The link is disabled in the last CRF in a visit for a patient.
	Close	The CRF and the DEW closes.

The DEW toolbar are there to assist you in performing data entry. The icons will be described in the sections of this Manual where their functions are utilized during data entry.

> ***TIP***: A few of the icons above require additional study privileges and may or may not function based on a user's assigned role.

Navigating within the Case Report Form (CRF):

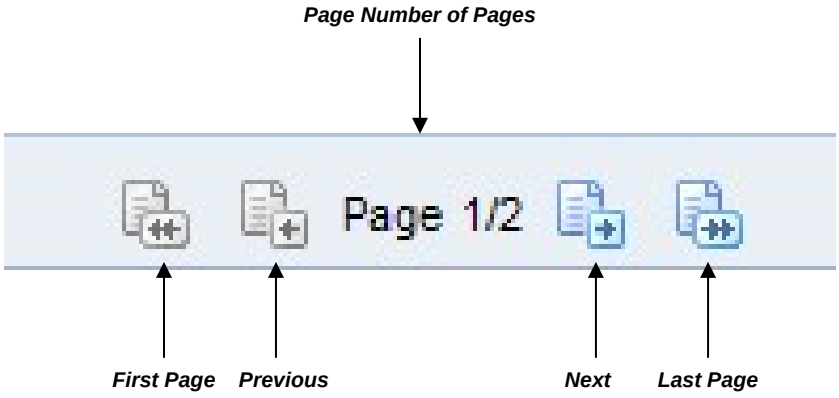
The Case Report Forms (CRFs) within the Data Entry Window (DEW) are replicas of the paper based study CRFs.

General layout of the CRFs within the DEW:

Vertical Scrollbar: Right of the open window if the CRF is too long to fit within the open DEW.

Horizontal Scrollbar: Bottom of the open window if the CRF is too wide to fit within the open DEW.

Page Navigation: In the DEW toolbar, if a CRF has multiple pages. The number of the current page is displayed against the total number of CRF pages. Navigate using the **Next**, **Previous**, or **Last Page** icons. See below:



General Data Entry with a Data Entry Window (DEW):

Using the Keyboard:

Tab: Move the cursor to the next data field available for data entry. The opened field will be outlined in gray.

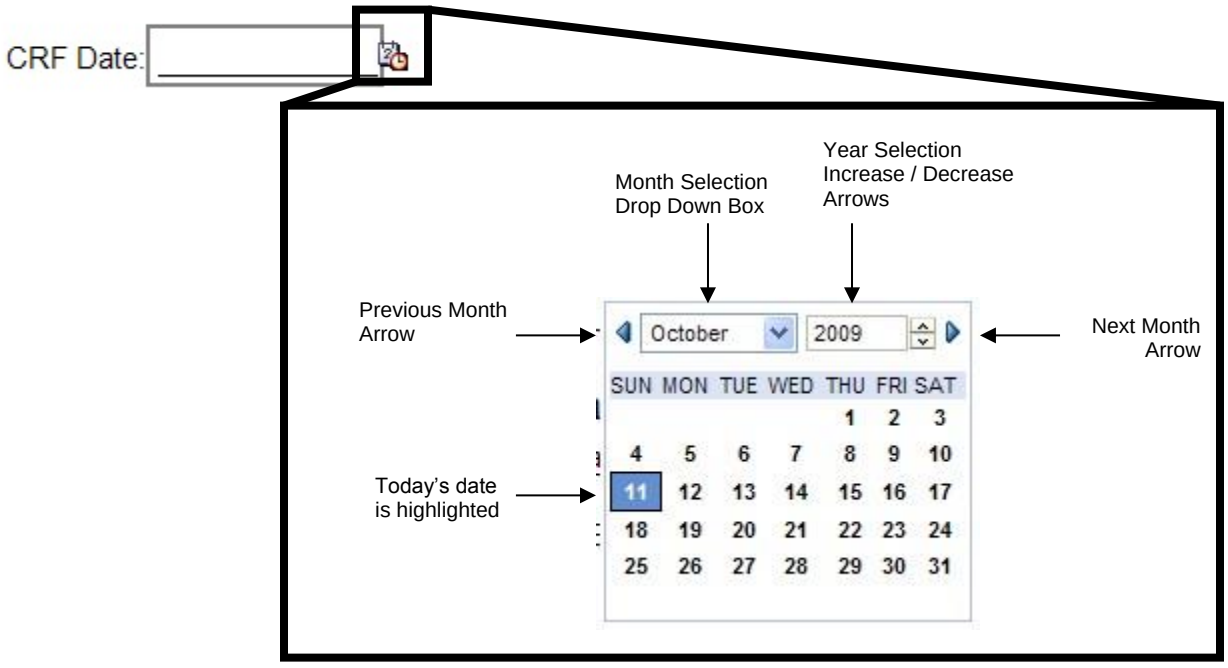
Shift Tab: Move the focus to the previous data entry field. The opened field will be outlined in gray.

Spacebar: Toggle a checkbox field on or off.

Using the Mouse:

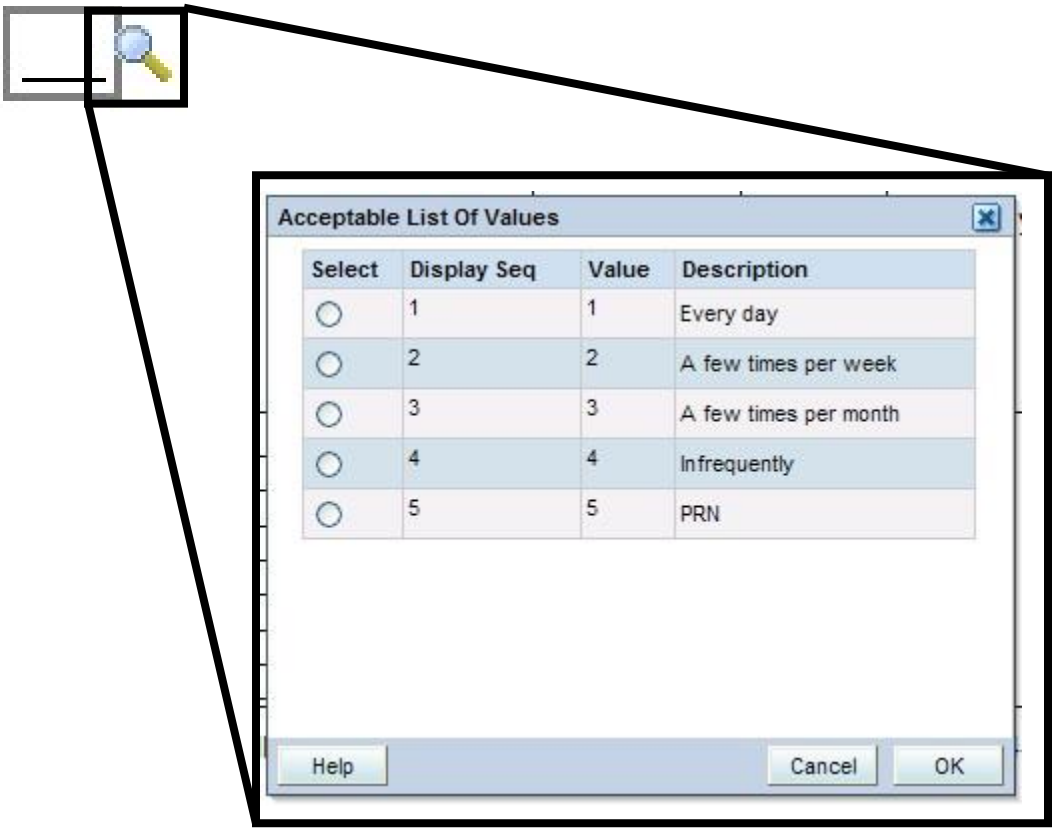
Left Click: Open the field for data entry. The opened field will be outlined in gray.

Date Fields: Click on the calendar icon to the right of the opened field to access the pop-up calendar window:


CRF Date:
Month Selection Drop Down Box
Year Selection Increase / Decrease Arrows
Previous Month Arrow
Next Month Arrow
Today's date is highlighted
October
2009
SUN MON TUE WED THU FRI SAT
1 2 3
4 5 6 7 8 9 10
11 12 13 14 15 16 17
18 19 20 21 22 23 24
25 26 27 28 29 30 31

- Navigate to the appropriate *Month* (Month Selection Drop Down Box) and *Year* (Year Selection Increase / Decrease Arrows).
- Click on the Day and the date will populate in the field.
- or manually enter the date in the opened date field instead of opening the calendar pop-up window.

List of Values: Some fields have lists of study-defined values associated with the data entry field. A magnifying glass icon at the right of the opened field indicates the field has an associated List of Values (LOV). Click on the icon to access a pop-up LOV window:



- Click the radio button in the SELECT column for the answer of a ROW.
- The “VALUE” field in the LOV pop-up indicates the numeric value of the answer associated with the paper-based CRF (the small number to the right of a check box).
- or manually enter this number in the opened field instead of using the LOV pop-up window.

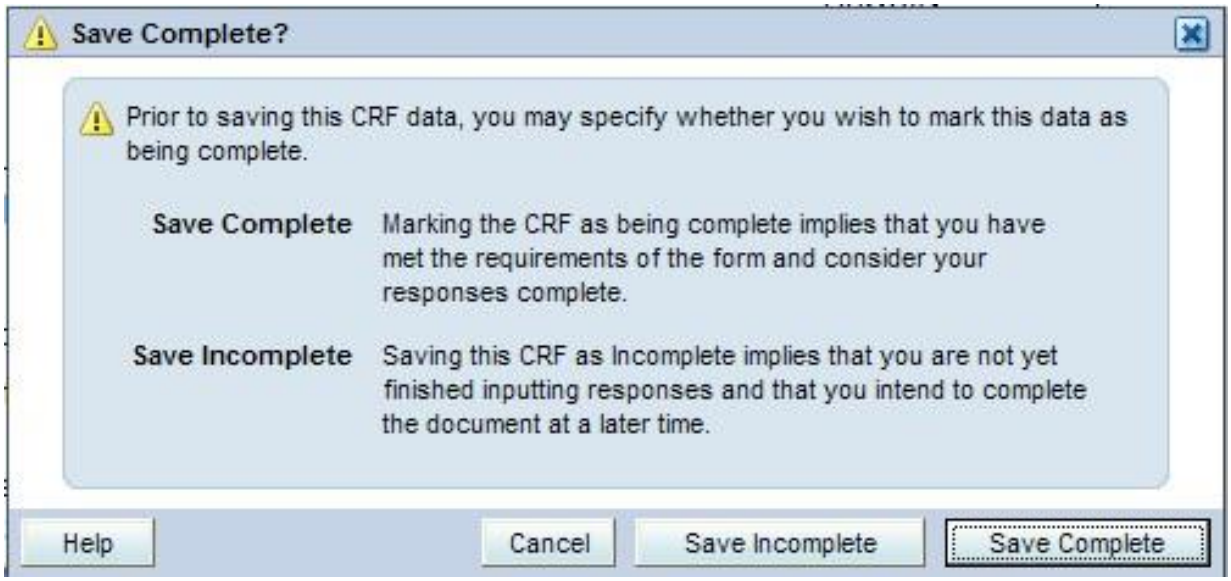
Entering data in a CRF:

All CRFs – either Empty or Entered – contain basic study related information: Study Name, Logo, Site Name / Number, Patient Identification Number (PID), CRF Name, etc. You are only required to enter responses to the remaining CRF questions.

To enter data in a CRF:

1. Click on a field to enter or update information.
2. Enter the data.
3. Use the Keyboard or Mouse to navigate from the field after adding or changing a value.
4. After all of the data has been entered or updated, click on the Save Data Icon in the toolbar.

Confirm ***Save Data*** using the ***Save Complete*** pop-up window:


Save Complete?
Prior to saving this CRF data, you may specify whether you wish to mark this data as being complete.
Save Complete
Marking the CRF as being complete implies that you have met the requirements of the form and consider your responses complete.
Save Incomplete
Saving this CRF as Incomplete implies that you are not yet finished inputting responses and that you intend to complete the document at a later time.
Help
Cancel
Save Incomplete
Save Complete

5. Select ***Save Incomplete*** or ***Save Complete***:

   Save Complete – indicates that all of the data for a CRF have been entered.

   - Selecting this option if all the data fields for the CRF are complete.
   - Discrepancy management will run on the CRF and highlight any discrepancies in red. ***Any data changes made to a field after the CRF has been saved as complete will need to be documented in Audit Trail Dialogue boxes indicating the "Reason for Change" (described in 5c of this section of the Manual).***

   Save Incomplete – indicates that data has been entered but is *not considered complete*.

   - Select this option to save entered data to the study database, and that you intend to complete the document at a later time.
   - The Audit Trail Dialogue does not pop-up for any data changes or updates.

Navigating between CRFs:

While in an open Data Entry Window (DEW), you can move from one CRF to another without closing the DEW and reopening a new CRF:

1. Click on the ***Previous CRF*** or ***Next CRF*** links in the upper right corner:

The ***Previous CRF*** or ***Next CRF*** opens in the same DEW and will move you backward or forward through the CRFs displayed in the Casebook Spreadsheet.

These navigational links are restricted to CRFs for a single patient and visit, and these links are only available to CRFs opened from the Casebook Page.

To change patients or visits:

Open additional DEWs for the patients and/or visits:

2. Select the CRF icon from the Casebook Spreadsheet, or

3. Close the current DEW (click the red X in the toolbar) and open up a new DEW.

Updating Existing Data in a CRF:

Data updates for existing CRF data can be performed from either the Casebook Page or the Review Page within the RDC Onsite application.

To update a data field:

1. Enter the CRF to be updated.

2. Select the data field to be updated.

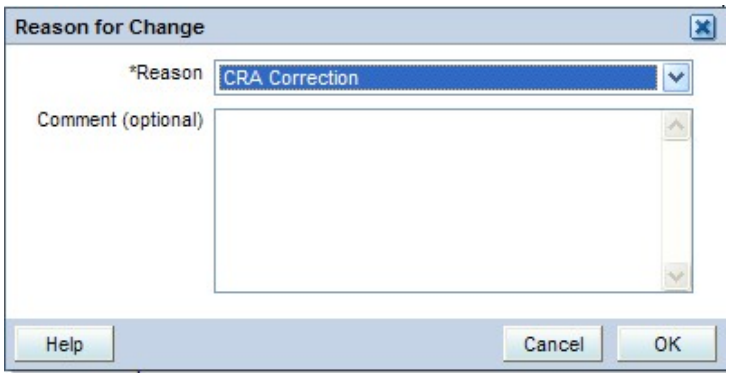
3. Change the value of the response.

4. Continue data entry if multiple values need to be entered or updated, or
   click the Save button in the toolbar.

Depending on the status of the CRF, RDC Onsite will respond accordingly:

CRF Previously Saved Incomplete – the system will accept the updates and prompt you to save the data using either the ***Save Complete*** or ***Save Incomplete*** options.

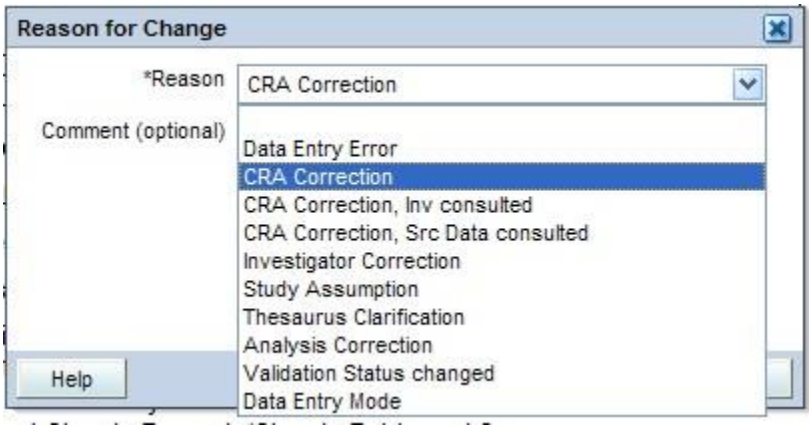
CRF Previously Save Complete – the ***Reason for Change*** pop-up window will open:



The ***Reason for Change*** is used as a way to provide additional information regarding changes made to data that has been ***Saved Complete***. This additional information, along with the prior value and updated value, gets added to the Audit Trail history and allows for a more comprehensive understanding for data changes made at the site level.

To complete the Reason for Change:

1. Click the downward arrow beside the **Reason** field to view a dropdown list:



2. Select a reason from the dropdown list to populate the **Reason** field. This is a mandatory field and RDC Onsite will not accept the change without a **Reason**.
3. Enter a comment in the **Comment** text box. Use this comment field to provide additional information, if needed, about the change being made.
4. Click **OK** to process the data change.

Marking a CRF as Blank:

In very rare circumstances, you may need to mark a CRF as intentionally blank. When marking a CRF as blank, all of the enterable data fields are "grayed out" and the data fields become inaccessible.

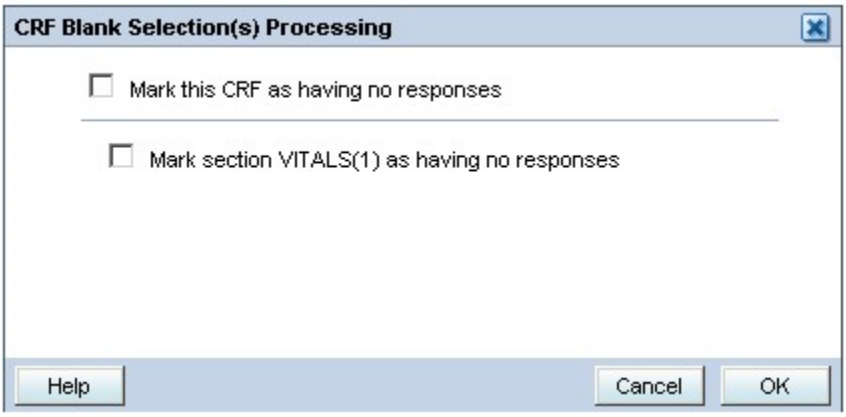
To mark a CRF as blank:

Use the ***Blank Flag*** Icon in the ***DEW Toolbar***:

1. Open a CRF from the Casebook Spreadsheet
2. Select the ***Blank Flag*** icon from the DEW toolbar.

   A CRF Blank Selection(s) processing dialog appears with these choices (example below):

   - Mark this CRF as having no responses.
   - Mark the *Section Name (Number)* as having no responses – this pertains to CRFs with multiple sections (for example: extensive Medical History).

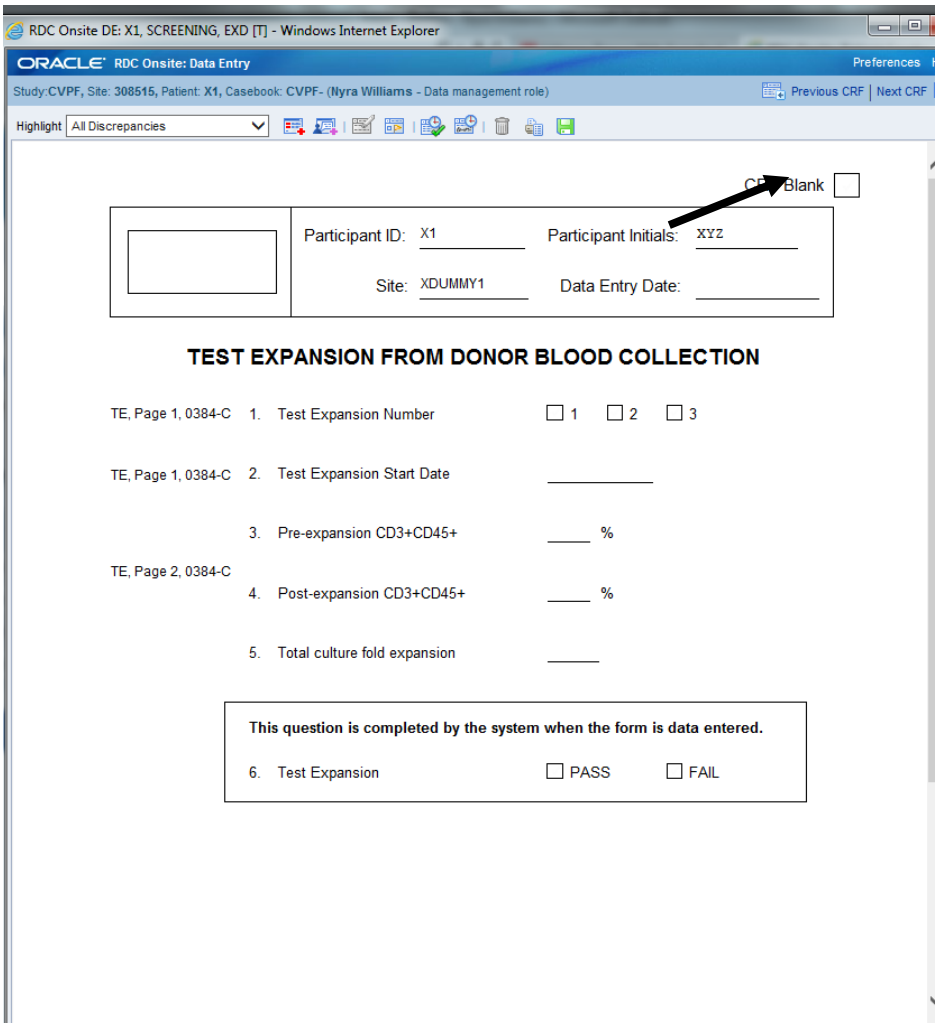


3. Check the box to make the selection – typically: ***Mark this CRF as having no responses***.
4. Select ***OK***.

   The CRF will be marked blank, associated fields are grayed out, and cannot be updated.

Using the Blank Flag Checkbox in the ***CRF***:

Depending upon the design of the CRFs approved for the study, a ***CRF Blank*** checkbox will appear in the header of the CRF.


RDC Onsite DE: X1, SCREENING, EXD [T] - Windows Internet Explorer
ORACLE RDC Onsite: Data Entry
Preferences
Study:CVPF, Site: 308515, Patient: X1, Casebook: CVPF- (Nyra Williams - Data management role)
Previous CRF | Next CRF
Highlight All Discrepancies
Blank
Participant ID: X1
Participant Initials: XYZ
Site: XDUMMY1
Data Entry Date:
TEST EXPANSION FROM DONOR BLOOD COLLECTION
TE, Page 1, 0384-C 1. Test Expansion Number 1 2 3
TE, Page 1, 0384-C 2. Test Expansion Start Date
3. Pre-expansion CD3+CD45+ %
TE, Page 2, 0384-C
4. Post-expansion CD3+CD45+ %
5. Total culture fold expansion
This question is completed by the system when the form is data entered.
6. Test Expansion PASS FAIL

1. Open the CRF from the Casebook spreadsheet

2. Check the ***CRF Blank*** box in the upper right corner of the CRF to make the selection.

The CRF will then be marked blank, associated fields are grayed out, and cannot be updated.

Changing the Status from Blank to Enterable:

To enter data in a CRF marked Blank,

1. Deselect the ***CRF Blank*** check box.

or Deselect the ***Blank flag*** icon

If the Blank CRF was saved as ***Entry Complete***, and you either deselect the ***Mark this CRF as having no responses*** box***,*** or deselect the ***CRF Blank*** checkbox in the header, you will be prompted to provide a ***Reason for Change***.

Inserting Missed Visit or Telephone Visit CRFs

There are two instances where you may need to insert a form onto a visit. One form that may need to be added is a Missed Visit Form if a patient fails to have a study visit within the time window. The Missed Visit Form must be inserted onto the visit that is actually missed.

The Telephone Visit Form (TF) may need to be inserted onto a visit for a required call 1 month after the last study visit. The Telephone Visit Form already exists on the 9, 15, and 21 month visits.

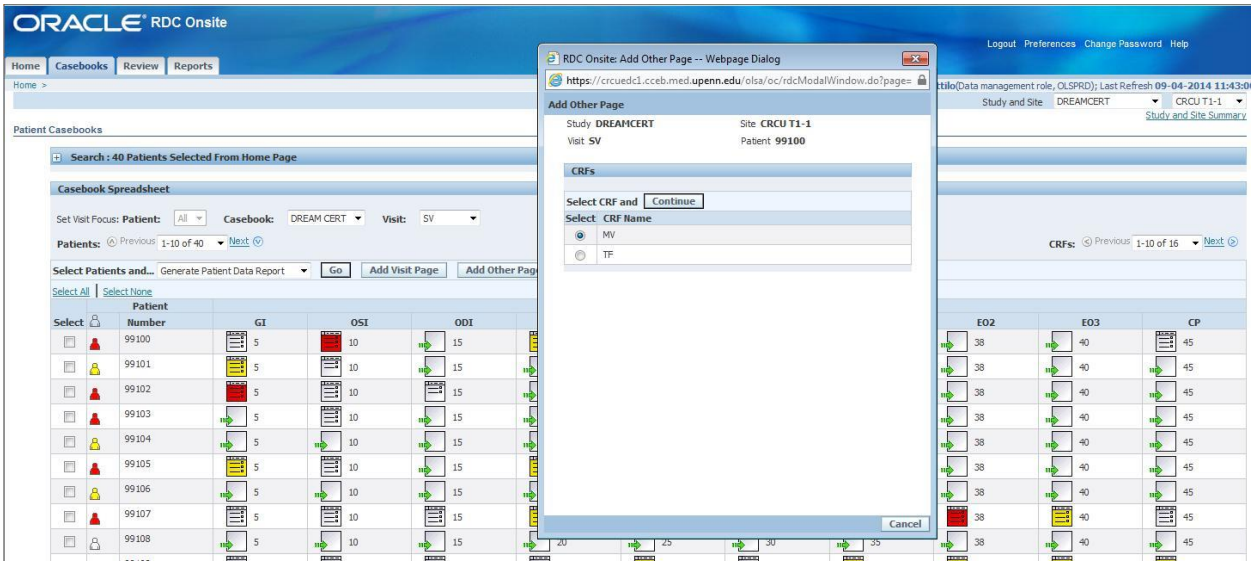
To insert a MV or TF form:

1. Select a visit from the **Visit** dropdown list.

2. Check the **Select** box to select a patient in the Casebook Spreadsheet.

3. Click the **Add Other Page** button in the control box.

   The Add Other Page dialog opens, listing all of the unplanned CRFs that can be added to the current visit for the selected patient. The dialog also displays the study and site name.



4. Select a CRF by clicking the radio button next to the CRF name.

5. Click **Continue**. The dialog closes and returns to the Casebook Spreadsheet.

6. Click the new CRF icon to open the icon in a DEW.

7. Enter data and save the CRF.

Discrepancy Management

Discrepancy management refers to an electronic process that systematically addresses data entry discrepancies within study CRFs. Data entered into the RDC Onsite application is evaluated against a set of study-defined expectations for each response field (answer on the CRFs). The application will trigger discrepancy management and create displayable messages regarding the discrepancy for reconciliation.

Discrepancy Types

There are two types of discrepancies that operate within the RDC Onsite application – ***Simple (Univariate)*** and ***Complex (Multivariate)*** discrepancies:

Simple (Univariate) – Discrepancies that are dependent on the value of a single data point.

- Simple discrepancies usually relate to the format of the data entered, to missing data in required fields, or to an unexpected value entered into a defined field.
- Simple discrepancies are triggered in real time and cause a dialogue box to be displayed while the user is performing data entry.

Example – Entering an invalid date such as 04/31/2014.

Complex (Multivariate) – are discrepancies that are dependent on two or more data point values, which can be within a single CRF or across multiple CRFs and / or visits.

- Complex discrepancies relate to missing data, to data that does not correlate with other data within a CRF or across CRFs, or to significant differences in data across time for patient safety.
- Complex discrepancies are triggered when a CRF is saved, causing fields and icons to be flagged in red or yellow.

Example – selecting male as the gender and selecting yes to “Is the patient a women of childbearing potential?”

Discrepancy Status

There are several discrepancy statuses that operate with the RDC Onsite:

Icon	Color	Description
	White	Patient data contains no open discrepancies.
	Gray with a question mark	No data have been entered for this patient.
	Yellow	Patient data includes discrepancies involving eligibility criteria, which requires your attention.
	Red	Patient data includes discrepancies involving non-eligibility criteria, which requires your attention.

Open Discrepancies appear in two formats:

- **Active** – a discrepancy that requires action or resolution based upon data that have been entered and validated. These discrepancies produce red icons and highlight the discrepant data in red.
- **Other** – a discrepancy that requires action or resolution based upon data that relates to eligibility criteria. These discrepancies produce yellow icons and highlight the discrepant data in yellow.

Closed Discrepancies represent discrepancies that have been resolved:

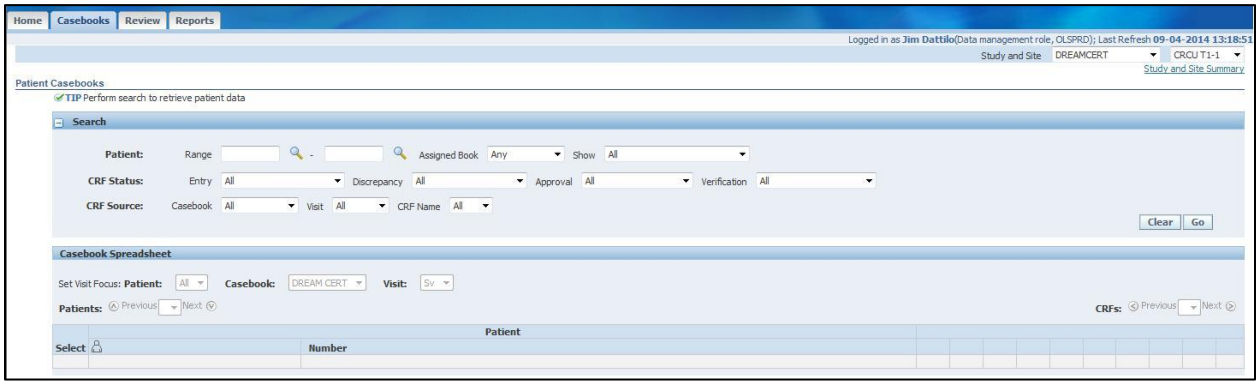
- ***Resolution of discrepancy*** – data updated or modified in accordance with edit checks. The red highlight of the field will disappear if a discrepancy has been resolved.
- ***Affirmation of discrepancy*** – an open discrepancy based on "unexpected" data results entered into CRF fields can be confirmed to be valid values and the discrepancy can be "Closed with no resolution". These fields will be highlighted in green.

Reviewing Discrepancies

In this section, finding and reviewing discrepancies will be discussed. Discrepancies can be reviewed from the two ***Surround Pages*** (*Casebook Page and Review Surround Page*) differently, to identify CRFs containing active discrepancies:

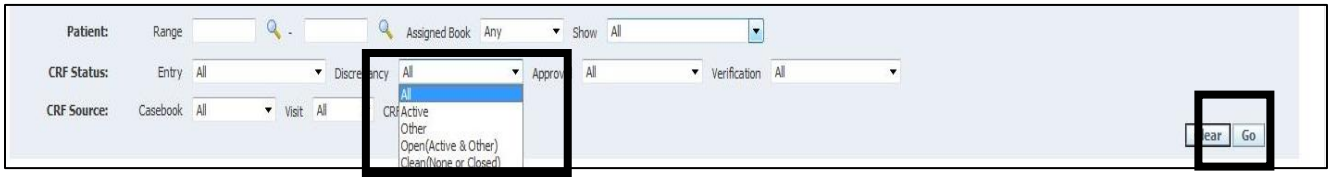
Casebook Page Surround Discrepancy Review:

The Casebook Surround Page organizes CRF icons in patient rows and CRF columns in casebook order. This organization can be useful in managing discrepancies on a patient-by-patient or visit-by-visit basis.



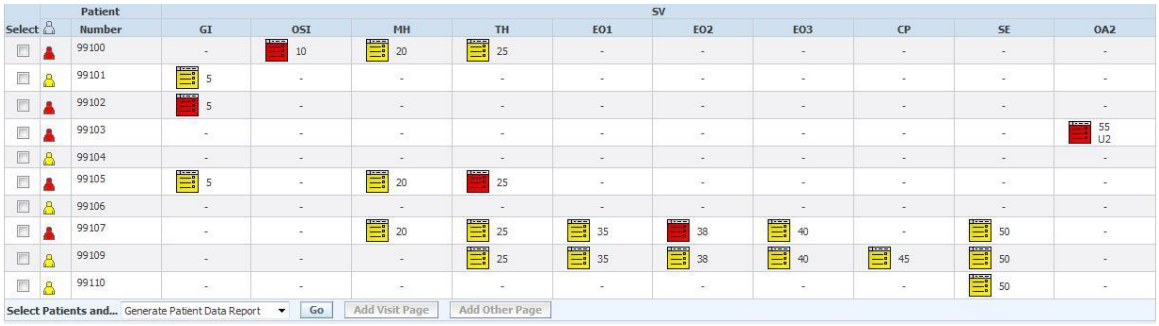
To find patients with active discrepancies:

1. Expand the Search section pane to specify a search for patients with active discrepancies.
2. Select ***Open (Active & Other)*** from the discrepancy drop-down of the CRF Status row.



3. Click **Go**.

   The Casebook Spreadsheet will display only those CRF icons with active discrepancies.

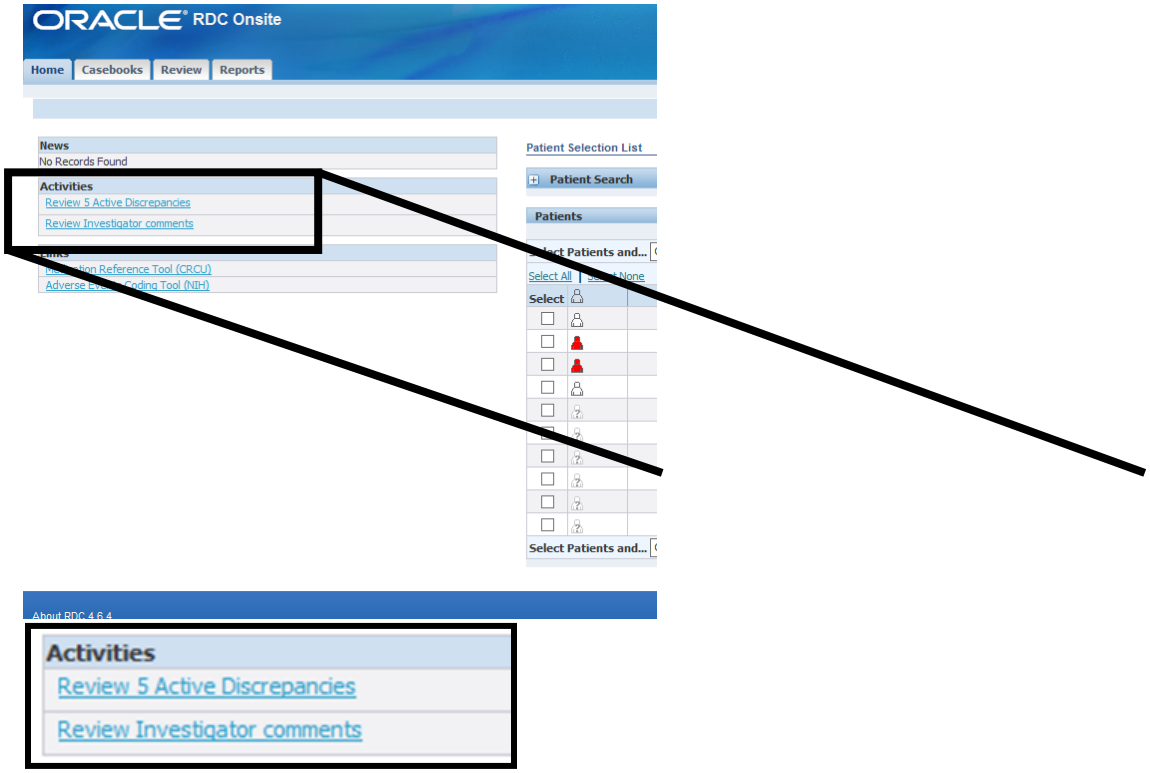


Select		Patient Number	SV									
			GI	OSI	MH	TH	EO1	EO2	EO3	CP	SE	OA2
☐		99100	-	10	20	25	-	-	-	-	-	-
☐		99101	5	-	-	-	-	-	-	-	-	-
☐		99102	5	-	-	-	-	-	-	-	-	-
☐		99103	-	-	-	-	-	-	-	-	-	55 U2
☐		99104	-	-	-	-	-	-	-	-	-	-
☐		99105	5	-	20	25	-	-	-	-	-	-
☐		99106	-	-	-	-	-	-	-	-	-	-
☐		99107	-	-	20	25	35	38	40	-	50	-
☐		99109	-	-	-	25	35	38	40	45	50	-
☐		99110	-	-	-	-	-	-	-	-	50	-

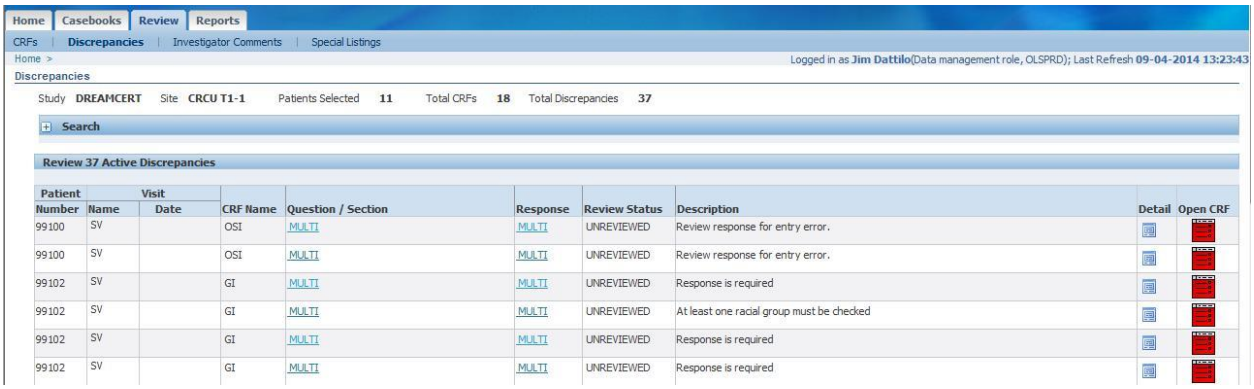
Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page

Review Page Surround for Discrepancy Review

The Review Discrepancies Page is especially useful in reviewing discrepancies across CRFs. To access this page, click on the hyperlink **Review [#] Active Discrepancies** from the **Activities** section on the Home Page.



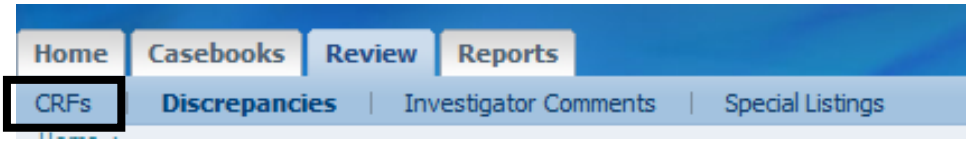
This hyperlink will open the ***Review Active Discrepancies*** view of the ***Review Surround Page***, listing all active discrepancies across all patients and CRFs for the site.


Home
Casebooks
Review
Reports
CRFs
Discrepancies
Investigator Comments
Special Listings
Discrepancies
Study DREAMCERT Site CRCU T1-1 Patients Selected 11 Total CRFs 18 Total Discrepancies 37
Search
Review 37 Active Discrepancies
Patient Number
Visit Name
Visit Date
CRF Name
Question / Section
Response
Review Status
Description
Detail
Open CRF
99100 SV OSI MULTI MULTI UNREVIEWED Review response for entry error.
99100 SV OSI MULTI MULTI UNREVIEWED Review response for entry error.
99102 SV GI MULTI MULTI UNREVIEWED Response is required
99102 SV GI MULTI MULTI UNREVIEWED At least one racial group must be checked
99102 SV GI MULTI MULTI UNREVIEWED Response is required
99102 SV GI MULTI MULTI UNREVIEWED Response is required

In the case above: 2 Patients, 2 CRFs, and 6 Total Discrepancies.

Working with the Review Page

The Review Page Surround provides easy access to review data entered in RDC Onsite via one of the 4 topical areas:

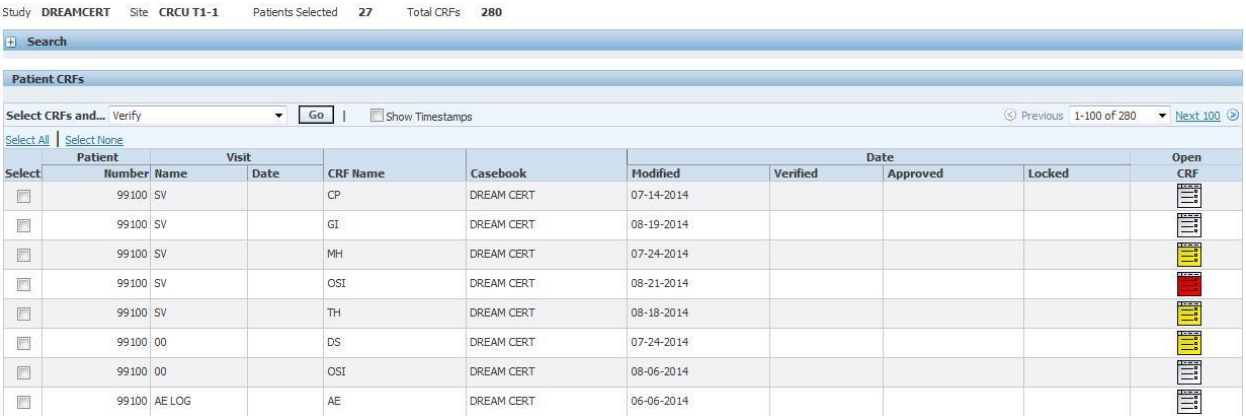


CRFs: View Audit Trail History about CRFs that have been entered and saved.

1. Use the Search pane of the Patient CRFs to view a sub-set of data or all entered data.

2. Click **Go**

The Patient CRFs section will display information about the Search criteria. The screen below shows that for this study there are 4 current patients with data.


Study DREAMCERT Site CRCU T1-1 Patients Selected 27 Total CRFs 280
Search
Patient CRFs
Select CRFs and... Verify Go Show Timestamps
Previous 1-100 of 280 Next 100
Select All Select None

Select	Patient Number	Visit Name	Visit Date	CRF Name	Casebook	Date Modified	Date Verified	Date Approved	Date Locked	Open CRF
☐	99100	SV		CP	DREAM CERT	07-14-2014				
☐	99100	SV		GI	DREAM CERT	08-19-2014				
☐	99100	SV		MH	DREAM CERT	07-24-2014				
☐	99100	SV		OSI	DREAM CERT	08-21-2014				
☐	99100	SV		TH	DREAM CERT	08-18-2014				
☐	99100	00		DS	DREAM CERT	07-24-2014				
☐	99100	00		OSI	DREAM CERT	08-06-2014				
☐	99100	AE LOG		AE	DREAM CERT	06-06-2014				

The Patient CRFs section displays the following data in the columns:

Patient Number: Patient numbers listed in descending order.

Visit (Name & Date): Visit Name and Date CRFs entered. (Date is blank since it is not used for the DREAM study).

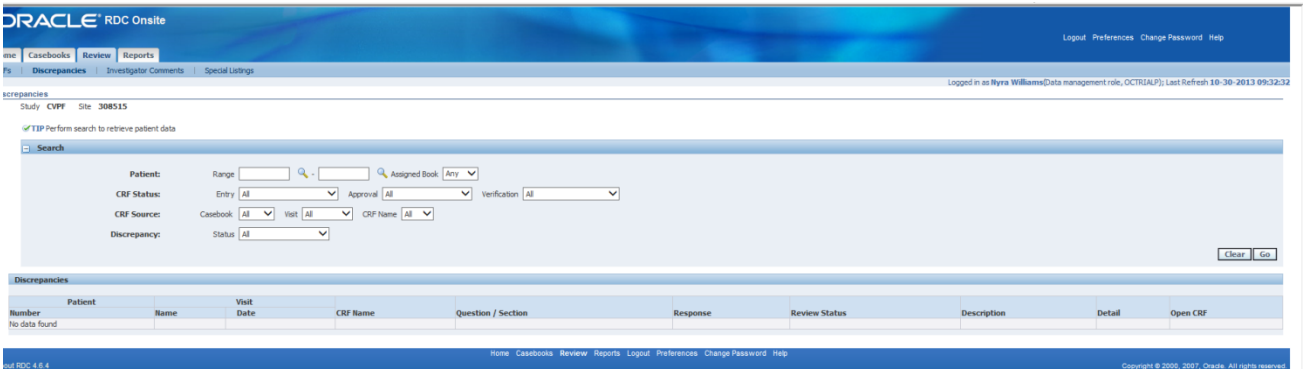
CRF Name: CRFs listed according to the order within a Casebook; in this case there several CRFs for this visit.

Casebook: Casebook or Study information

Date (Modified, Verified, Approved, & Locked): Dates of the most recent modification, verification, approval, and lock. Some of these dates may never be populated depending upon study use.

Open CRF: Hyperlink to a Data Entry Window (DEW) to update data or review discrepancies.

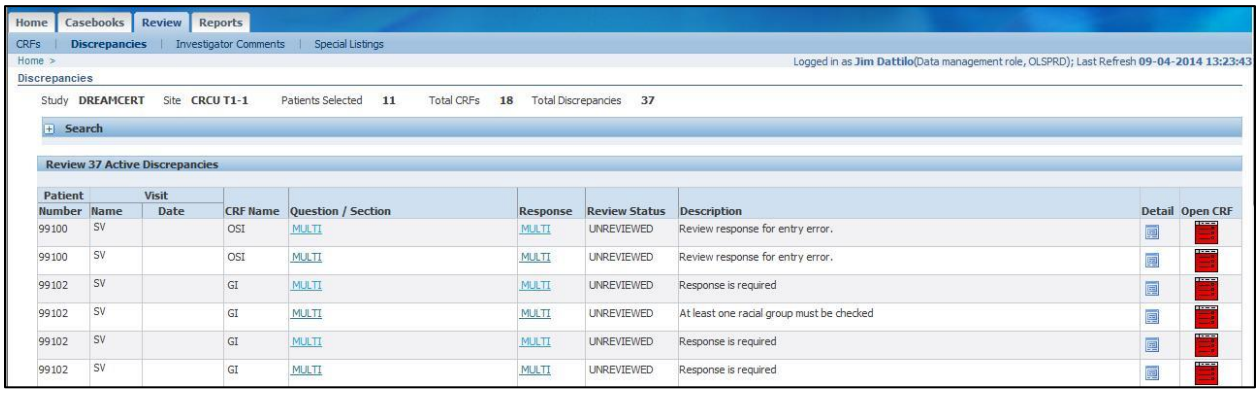
Discrepancies: Access to Search Discrepancies.



1. Use the Search section pane within Discrepancies to view a sub-set of data or all entered data.

2. Click **Go**

The Discrepancies section will display information about the Search selection criteria. The detail below shows that for this study there are 2 patients, 2 CRFs, and 6 total discrepancies



Patient Number	Visit Name	Visit Date	CRF Name	Question / Section	Response	Review Status	Description	Detail	Open CRF
99100	SV		OSI	MULTI	MULTI	UNREVIEWED	Review response for entry error.		
99100	SV		OSI	MULTI	MULTI	UNREVIEWED	Review response for entry error.		
99102	SV		GI	MULTI	MULTI	UNREVIEWED	Response is required		
99102	SV		GI	MULTI	MULTI	UNREVIEWED	At least one racial group must be checked		
99102	SV		GI	MULTI	MULTI	UNREVIEWED	Response is required		
99102	SV		GI	MULTI	MULTI	UNREVIEWED	Response is required		

The Discrepancies section displays the following data in the columns:

Patient Number: Patient number for the query; in this case there is one patient displayed on two rows.

Visit (Name & Date): Visit name and date of CRF entry.

CRF Name: CRF Name for the open discrepancies.

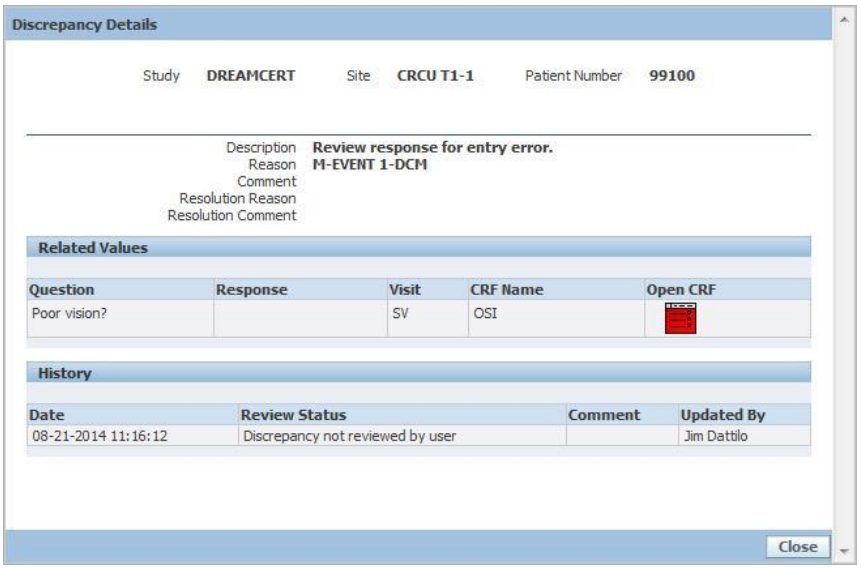
Question / Section: Hyperlink to open the Discrepancy Detail for more information.

Response: Hyperlink to view the Discrepancy Details for more information

Review Status: Display the discrepancies current review status.

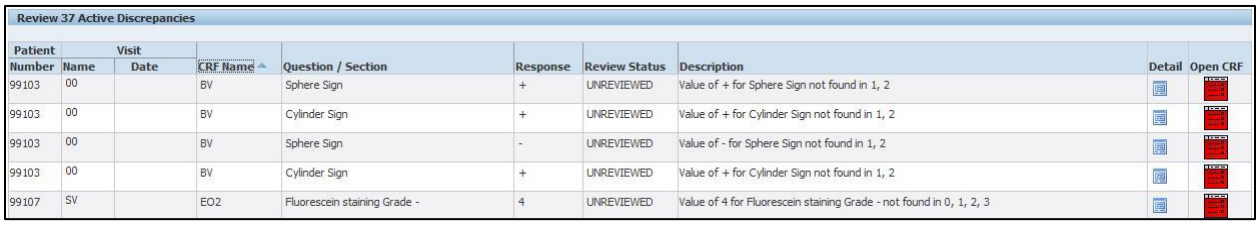
Description: Display the discrepancy message.

Detail: Open a review window to view related values and discrepancy history without opening the CRF:



Open CRF: Hyperlink to a Data Entry Window (DEW) to address the discrepancy or modify data.

Sort the displayed discrepancies by clicking on any column header:

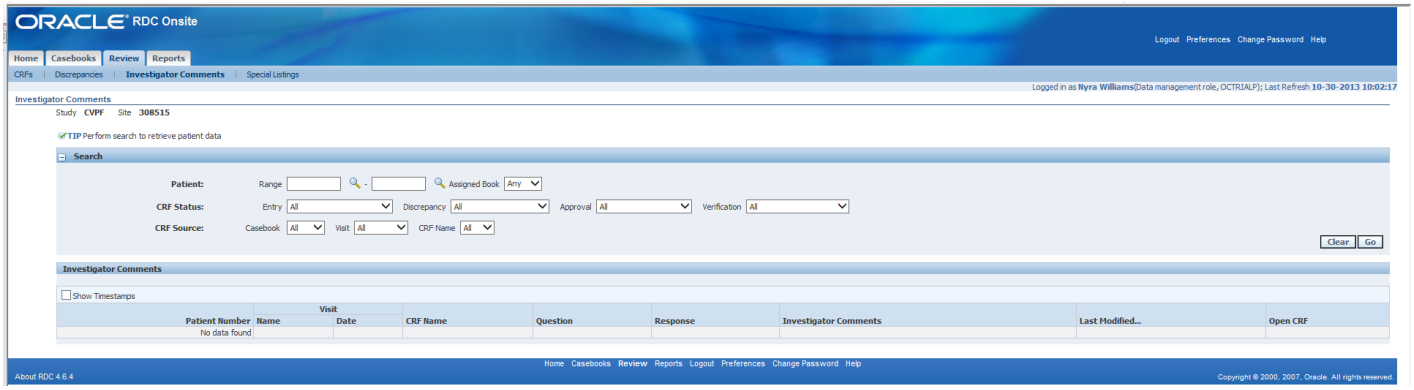


Patient Number	Visit Name	Visit Date	CRF Name	Question / Section	Response	Review Status	Description	Detail	Open CRF
99103	00		BV	Sphere Sign	+	UNREVIEWED	Value of + for Sphere Sign not found in 1, 2		
99103	00		BV	Cylinder Sign	+	UNREVIEWED	Value of + for Cylinder Sign not found in 1, 2		
99103	00		BV	Sphere Sign	-	UNREVIEWED	Value of - for Sphere Sign not found in 1, 2		
99103	00		BV	Cylinder Sign	+	UNREVIEWED	Value of + for Cylinder Sign not found in 1, 2		
99107	SV		EO2	Fluorescein staining Grade -	4	UNREVIEWED	Value of 4 for Fluorescein staining Grade - not found in 0, 1, 2, 3		

Sort or Search by:

- ***Patient*** to view a list of all discrepancies sorted by patient.
- ***Visit*** to view all discrepancies for a given ***Visit*** across patients.
- ***Review Status*** to view which discrepancies are currently open or currently in review.
- ***Description*** to find any view discrepancies based upon their error message.

Investigator Comments – View field level comments or notes that an Investigator, Monitor, or Reviewer deems appropriate to be included for a given value. This feature may or may not be used for a particular study.


ORACLE RDC Onsite
Logout Preferences Change Password Help
Home Casebooks Review Reports
CRFs Discrepancies Investigator Comments Special Listings
Logged in as Nyra Williams(Data management role, OCTRIALP); Last Refresh 10-30-2013 10:02:17
Investigator Comments
Study CVPF Site 308515
TIP Perform search to retrieve patient data
Search
Patient: Range Assigned Book Any
CRF Status: Entry All Discrepancy All Approval All Verification All
CRF Source: Casebook All Visit All CRF Name All
Clear Go
Investigator Comments
Show Timestamps
Visit
Patient Number Name Date CRF Name Question Response Investigator Comments Last Modified... Open CRF
No data found
Home Casebooks Review Reports Logout Preferences Change Password Help
About RDC 4.6.4
Copyright © 2000, 2007, Oracle. All rights reserved.

1. Use the Search section pane within Investigator Comments to view a sub-set of data or all entered data.

2. Click **Go**

The Investigator Comments (if there are any used for the study) section displays the following data in the columns:

Patient Number: Patient number for the query; in this case there is one patient displayed on two rows.

Visit (Name & Date): View the associated visit name and date of CRF entry.

CRF Name: View the CRF Name of the Investigator Comment.

Question: Hyperlink to open the Investigator Comment Detail for more information.

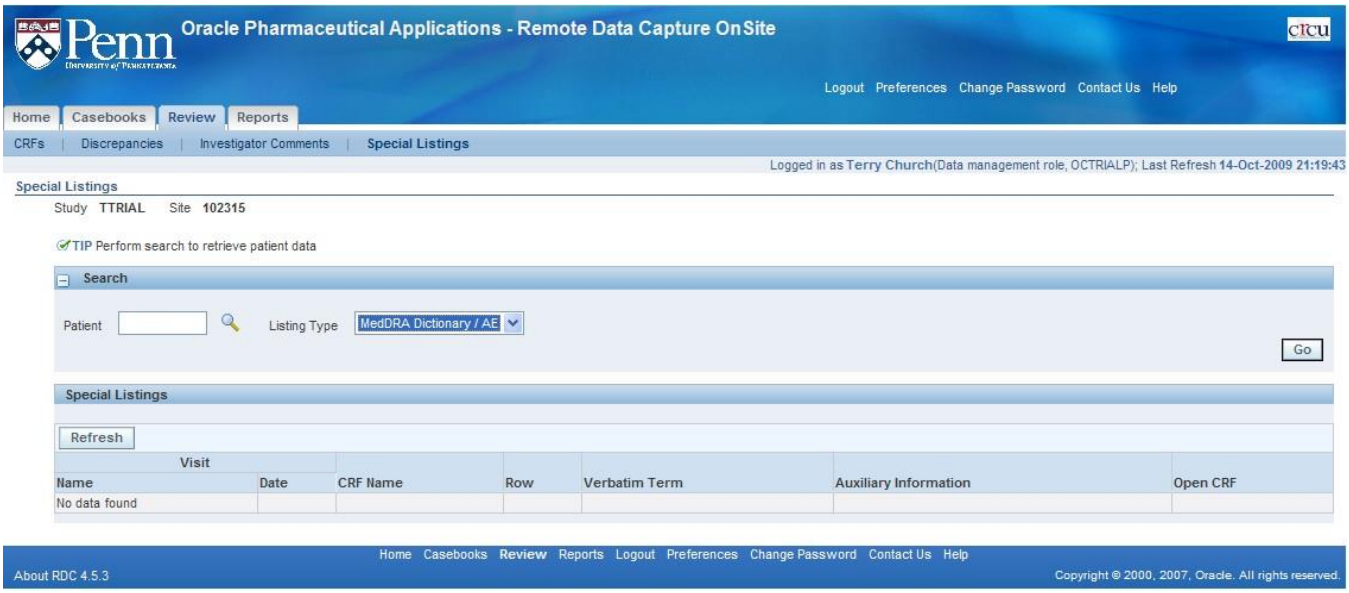
Response: Hyperlink to view the Investigator Comment detail for more information.

Investigator Comment: Display the associated comment for the Question.

Last Modified: Display the date the comment was last modified.

Open CRF: Open a DEW for the CRF and view the comment on the associated CRF.

Special Listings – View specialized questions. Examples may include Adverse Events or Concomitant Medications with coding errors that need to be reviewed and updated.

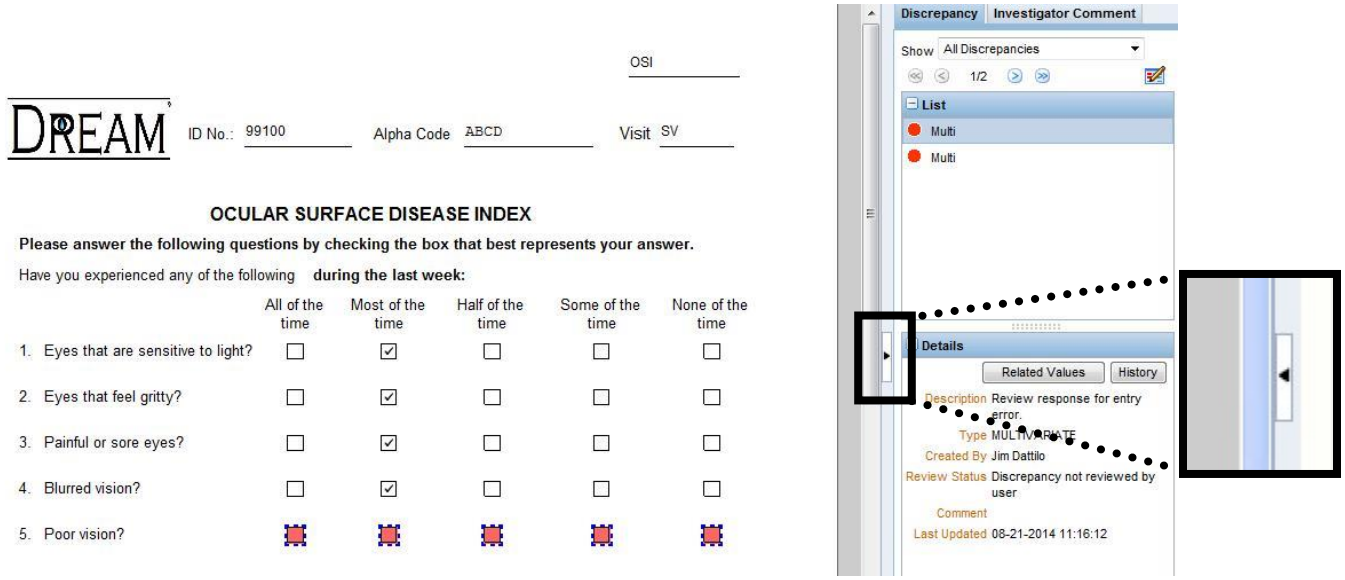


NOTE: Primarily, CRCU staff only use this area, therefore the functionality will not be described in detail.

Resolving Discrepancies

After a CRF with a discrepancy has been found, you will need to open it in a Data Entry Window (DEW). The CRFs with discrepancies can be opened from the Home Page Surround, the Casebook Page Surround, or the Review Page Surround as detailed in the previous sections.

- Use the ***Navigator Pane*** to review, in list format, all Discrepancies or Investigator Comments (if applicable for the study) for a CRF.
- By navigating through the list of Discrepancies or Investigator Comments, you simultaneously navigate through the associated fields in the CRF.



Using the Navigator Pane

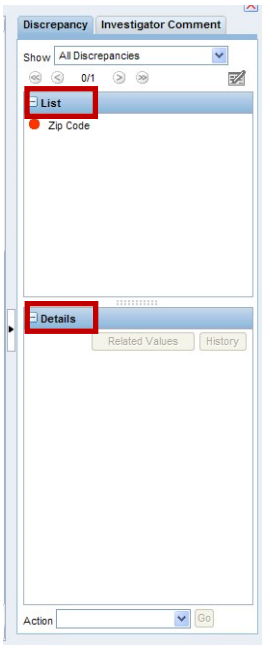
1. Click the arrow on the right edge of the DEW to open/close the ***Navigator Pane***:

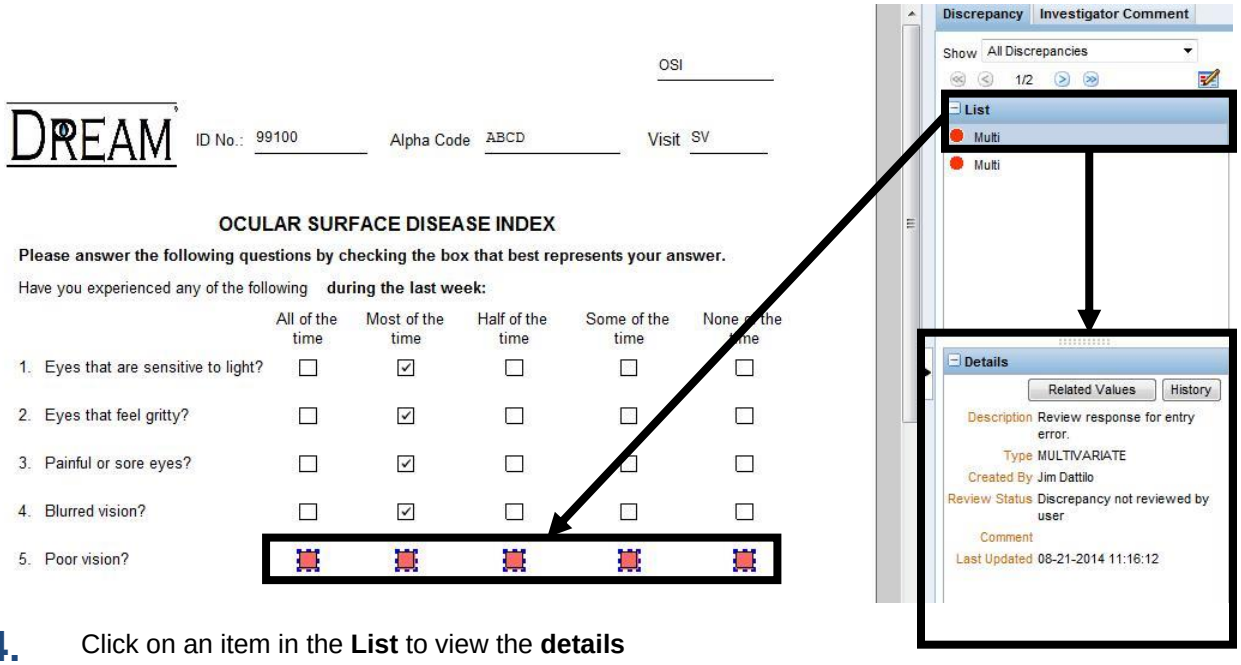
2. Select a tab, either ***Discrepancy Navigator*** or ***Investigator Comments*** Navigator.

There are two sub-panes of the Navigator: **List** and **Details**. These sub-panes help organize information and facilitate movement in the open CRF.

3. Click the nodes (**+** or **-**) next to the **List** or **Details** in the title bar of the sub-pane to collapse (**-**) or expand (**+**) the sub-pane windows.

- **List**: Lists discrepancies or investigator comments according to the tab selected. Click an item in the list to review the associated field within the CRF and activate the **Details** sub-pane.
- **Details**: View details of a selected discrepancy or investigator comment within this sub-pane. A scroll bar at the right edge of the sub-pane allows you to scroll through **Details**.





4. Click on an item in the **List** to view the **details**

Related Values opens a pop-up window listing any previously entered values for the same CRF at different visits to show values over time. In the example above, the button is not available meaning this field has no related values.

History opens a pop-up window listing the discrepancy history:

5. After the discrepancy has been reviewed, correct the data in the associated highlighted field appropriately.

A reason for change dialog box will appear.

6. Save the CRF and the discrepancy will automatically close.

Using the Navigator Pane to Respond to Discrepancies:

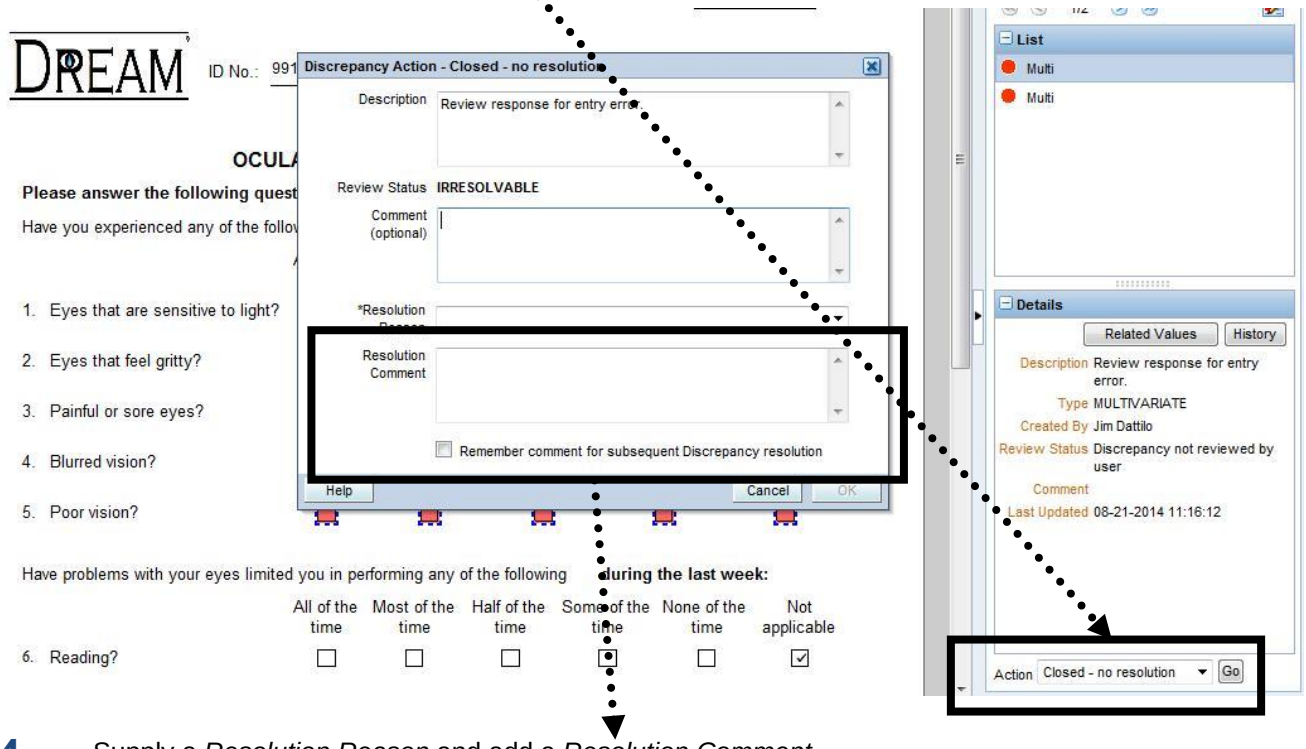
In some instance, data that triggered a discrepancy may be valid and you can document this within the Navigator Pane.

1. Click a CRF icon to open it in the DEW.

2. Open the Discrepancy Navigator and select the specific discrepancy.

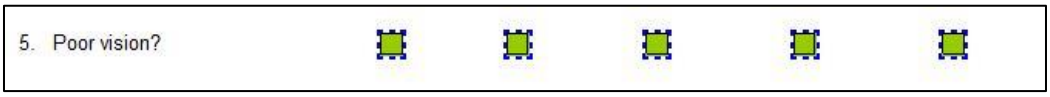
3. Select ***"Closed – no resolution"*** from the **Action** dropdown list at the bottom of the Discrepancy Navigator and then click ***Go***.

The Discrepancy Action dialogue box opens (see example below):



4. Supply a *Resolution Reason* and add a *Resolution Comment*

5. Click **OK**.



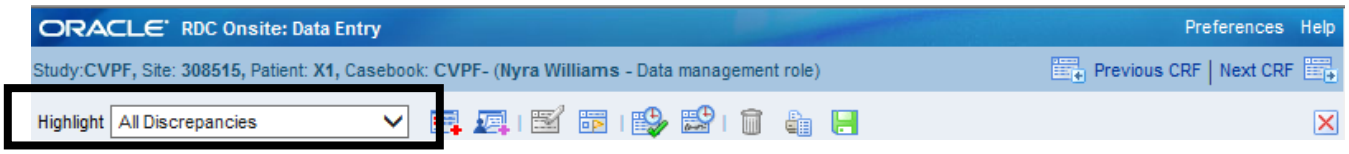
The field highlight will switch from red to green, and the Navigator Pane will display the Review Status as Irresolvable.

6. Save the CRF for the changes to take effect.

Using Highlights to Review Discrepancies

RDC Onsite highlights information in a CRF in different ways. To review a CRF using this feature:

1. Select the type of information to highlight from the **Highlight** dropdown selection list in the DEW toolbar.


ORACLE RDC Onsite: Data Entry
Preferences Help
Study:CVPF, Site: 308515, Patient: X1, Casebook: CVPF- (Nyra Williams - Data management role)
Previous CRF | Next CRF
Highlight
All Discrepancies

   Options are:

   - None,
   - Active Discrepancies,
   - Active and Other Discrepancies,
   - Closed Discrepancies,
   - All Discrepancies,
   - Investigator Comments,
   - Audit History, etc.

   RDC Onsite highlights the associated fields accordingly, facilitating a quick review of the CRF.

2. Navigate to the highlighted field.

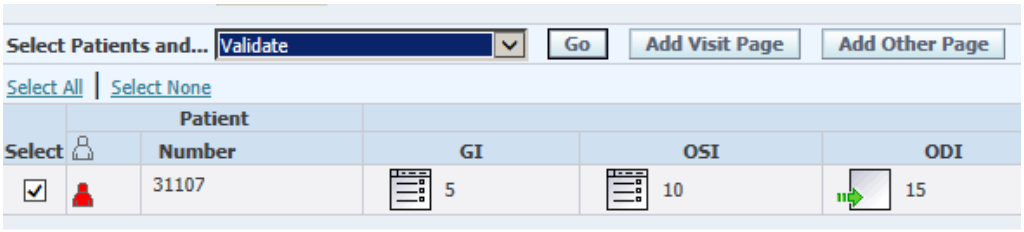
3. If the field is red, modify the data.

4. Save the CRF.

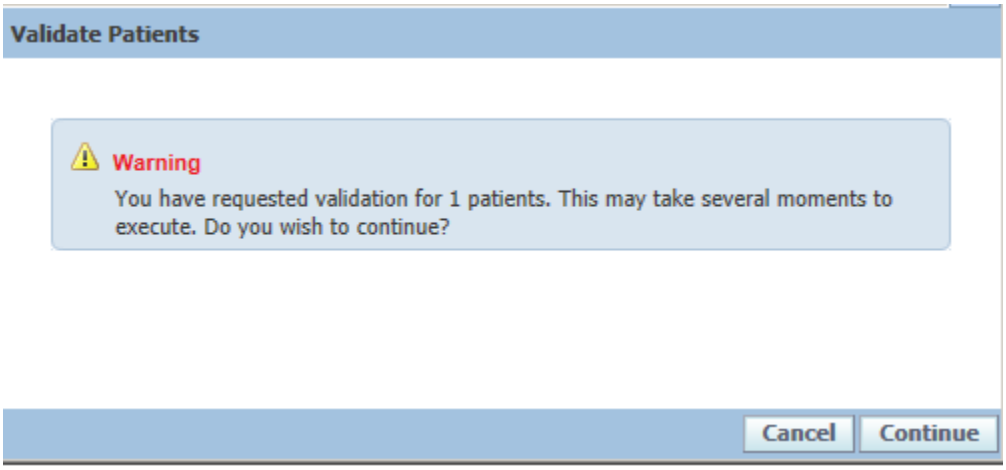
   If the new value is valid for a field, the associated discrepancy will automatically close.

Updating Discrepancy Validation

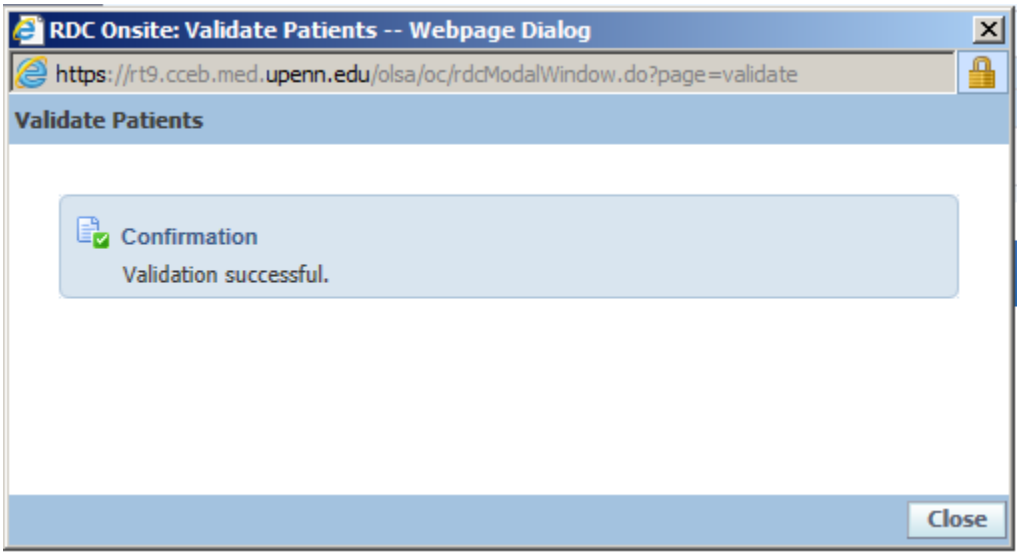
1) If you have saved complete the Screening Visit Eligibility Review or the Request for Randomization and need to update discrepancies in preceding forms, you may need to validate the record for the eligibility checks to be updated. To validate the record check the box under the select column and select Validate.



2) After clicking on Go you will receive a warning message. Click on Continue.


Validate Patients
Warning
You have requested validation for 1 patients. This may take several moments to execute. Do you wish to continue?
Cancel
Continue

3) When the validation is complete another message will be displayed. Click on close.



List of Abbreviations

AE	Adverse Event
CC	Coordinating Center
CCEB	Center for Clinical Epidemiology and Biostatistics
CDM	Clinical Data Management
CMED	Concomitant Medication Log
CRCU	Clinical Research Computing Unit
CRF	Case Report Form
DEW	Data Entry Window
DM	Data Manager
DMS	Data Management System
FDA	Food and Drug Administration
ICH	International Conference on Harmonization
IE	Internet Explorer
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INV	Investigator
MedDRA	Medical Dictionary for Regulatory Activities
NIH	National Institutes of Health
OC	Oracle Clinical
OPA	Oracle Project Administration
OS	Operating System
PC	Personal Computer
PDF	Portable Document Format
PI	Principal Investigator
PID	Patient Identification Number
QA	Quality Assurance
QC	Quality Control
RC	Research Coordinator
RDC	Oracle Clinical Remote Data Capture
SAE	Serious Adverse Event
SOM	School of Medicine
UPENN	University of Pennsylvania

Glossary[1]

A – B

Active — A *discrepancy status* that indicates the relevant discrepancy is actionable by members of your *user group*.

audit trail history — The set of all audit records for a given data point.

audit trail record — A set of information that describes an instance of data update. Each audit record includes the following information:

- the current value of the data point
- the previous value of the data point
- the username that changed the data point
- the timestamp the data update occurred
- the change reason
- an optional comment

Blank — An *entry status* designation that is assigned to a CRF a user has defined as blank. A Blank CRF does not contain data, nor can data be collected while it is marked as blank.

C

Cancel — A user action that halts the current process or action and reverts to the state of the application that immediately preceded the process or action, without changing the status of the system or data.

cancel button — In a dialogue or pop-up window, a cancel button causes the application to dismiss the window, disregard changes made in the window, and revert to conditions that existed before the window opened.

Casebook — The set of CRFs that are used to collect data for a patient over the course of the study. Each *patient* is assigned to a particular case book.

case report form (CRF) — A paper or electronic record associated with a patient in a study. Its purpose is to facilitate accurate collection of clinical data. CRFs are accessed through the PDF data entry window.

change reason — A constituent of an *audit record*. A standardized entry that explains why a data point changed. The change reason can be supplied either automatically (system-provided) or manually (user-provided). A user-supplied change reason is required when patient data changes after the CRF reaches *entry complete* data entry status.

[1] Abridged version of the Glossary from the *RDC User Guide*.

Clinical Research Computing Unit (CRCU)

The Clinical Research Computing Unit (CRCU) is a designated core research facility providing state-of-the-art scientific services related to clinical data management and research computing. The CRCU is staffed with project management, clinical data management, and research computing professionals who support the development and implementation of large-scale, multi-center clinical trials, collaborative clinical and patient-oriented research, and multi-institutional health services research projects for Penn Medicine, which encompasses the CCEB, the School of Medicine, and the University of Pennsylvania Health System (UPHS). The development and support activities of the CRCU involve application development, database administration, project management, clinical data management, research computing, and technology support services.

closed

A *discrepancy status* that indicates the relevant discrepancy is not actionable by any *user group*. The discrepancy has been resolved, either by a user or the system.

CRF header

An area of a CRF which consists of information that identifies a given CRF and the data that it collects. The information pertains to the patient, visit, investigator, and site. Much of the information included in the header is displayed in Patient Workbook Report, which allows you to print a casebook for a specific patient.

In the data entry windows, certain fields in the CRF header are required, that is, you must record that information before the system allows you to save the CRF.

RDC Onsite will not save a CRF to the study database until all required CRF header and CRF section header fields are collected.

current

A discrepancy stat that indicates action can be taken on the discrepancy – either by a user or by the system.

current study

The data set that is active. The name of the current study is displayed in the title bar of the Main Application Window.

D

data entry mode

A designation that describes the method that is used to enter data into a CRF and save it to the study database.

data entry status

A designation that describes the current state of data entry for a CRF. There are four data entry statuses:

1. created
2. blank
3. entry started
4. entry complete

data field

A location in the Question area of the Data Entry window in which you type a value that is the response to a CRF question.

data point

A location in a form where a data value may be entered. In most cases, a data point corresponds to a field in the data entry window.

data update

The process of changing a CRF that has been *created* and saved to the database by altering a *data point* and saving the new version of the CRF to the database.

discrepancy

Data that falls outside of an expected range of values or is otherwise "flagged" during the edit check process.

discrepancy management — A process that systematically addresses discrepancies generated within a study. Discrepancy management attempts to identify the cause and assess the implications of each discrepancy and determine an appropriate action for the discrepancy. Its goal is to satisfactorily resolve all discrepancies associated with each CRF.

discrepancy record — An entry which is part of the study database that defines the pertinent aspects of a discrepancy, from its initial occurrence and through each action that is taken on it.

discrepancy status — A designation that describes the current state of a CRF with regard to discrepancies. There are four discrepancy statuses:

1. none
2. closed
3. active
4. other

E – F

electronic data capture (EDC) — A method of data collection for studies that uses computers at investigator sites as a mechanism to submit patient data and information to a centralized study database. Remote Data Capture (RDC) is an electronic data capture application.

entry complete — An *entry status* that is assigned to a CRF in which all required fields have been entered, including CRF header fields and Question area response data points.

entry started — An *entry status* that is assigned to a CRF in which data entry has been initiated but is not complete. CRFs that are assigned this entry status, some required data fields are complete, while some are not; the document has been saved in an incomplete status.

entry status — Formal stages of data entry, delineated in RDC, that track the progression of a CRF from no data entered (“created”) through entry complete.

filter — A *saved search* that is applied to the Activity List window to limit the scope of the Navigation page and / or the activities that is available in the Task pane. It allows you to generate a more discrete and focused *work set* that is still based on an activity.

focus — Where the cursor is currently active. Focus may change from window to window, as when the cursor moves from the Main Application window to the first data field in the Data Entry window when you click a CRF cell.

H – I

header field — A location in the CRF header in which you collect values that provides information about the CRF. All required header fields must be collected before the system permits a CRF to be saved to the study database.

indicator question A question used with certain *question groups* that allow "branching" during data entry based on the response.

For example, in a Drug Allergy question group, an indicator question could be, "Are you allergic to any drugs?"

- If the response is "Yes", the remaining questions in the question group, such as "Drug Name" and "Type of Reaction", require responses
- If the response is "No", the rest of the question group is not collected.

L

list of values (LOV) A set of possible values for a data field. The list of values can generally be displayed by either clicking the button associated with list of value fields, pressing the List button, or by pressing the F9 key.

M

manual discrepancy A *discrepancy* that is generated by a user, rather than a *data point* value. A manual discrepancy may be associated with an entire CRF, a CRF header, or a specific response in the question area of a CRF.

MedDRA The *Medical Dictionary for Regulatory Activities* – is a pragmatic, medically valid taxonomy of medical terms with an emphasis on ease of use for data entry, retrieval, analysis, and display, as well as a suitable balance between sensitivity and specificity within the regulatory environment. It allows for uniform coding and reporting of medical signs, symptoms, and body systems for Adverse Event (AE) reporting. It was developed by the International Conference on Harmonization (ICH) and is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as trustee for the ICH steering committee.

multivariate discrepancy A *discrepancy* that is dependent on two or more *data point* values, which can be within a single CRF or across multiple CRFs and / or visits. A multivariate discrepancy is generated when a CRF is saved, which causes the system to run the validation procedures that locate this type of discrepancy.

N – O

news item A message that is communicated by the study sponsor to some portion of its RDC Onsite application users. News items are displayed in the News window.

open A designation for a *discrepancy* that indicates it is either in the *active* or *other* discrepancy status; that is, it is actionable by a *user group*.

A designation for a CRF that indicates it contains at least one *active* or *other* discrepancy.

P

parameter A component of a *criterion* that you use to define a specific property of the data you wish to comprise the *work set*. A parameter may be comprised of settings that represent a value or range of values that, when combined with

any other parameters in the same criterion, define specific data.

patient A human participant in a study. In RDC Onsite about whom data is collected. Each patient in a study is assigned a unique patient number that is associated with a particular site. In addition, the patient number is also assigned to a particular case book.

patient data The data that is collected about a participant in a study. This includes demographic information and clinical results.

patient list The set of patients that contain at least one CRF which satisfies the search criteria.

patient number A designation for a set of patient data that is unique across a give study. Patient numbers are assigned to a study as part of the design process. Alternative terms include – patient positions, enrollment number, allocation number, and randomization number.

The following rules apply to all patient numbers:

1. Each patient number must always be assigned to a site.
2. Each patient number may not be assigned to more than one site at a time.
3. The first character in the patient number string may be a non-zero numeric or an alphabetic character.
4. If the first character in the patient number sting is alphabetic, the second character must be a non-zero character.
5. Only the first character may be alphabetic.

pending changes Changes that are made to a CRF that have not yet been committed to the study database. The changes that may be pending are response value, investigator comments, or discrepancies. The *save* action commits pending changes to the database.

privilege The ability for a user to perform a certain task. Privileges are granted to users in the Administration study and site maintenance windows by administrators. In general, users within a *user group*, that is, those that are given the same *role*, are assigned the same set of privileges.

The specific sequence that is employed at any time is defined by the Progression to next CRF setting in the Preferences window. In PDF mode, the browse sequence is invoked when you use the Previous and Next buttons.

Q – R

query A term that is a synonym for *discrepancy*. A procedure that is run against a database with the goal of returning a subset of data that satisfies the query criteria.

resolution A type of *discrepancy action* that causes the status to change from *active* to *closed*.

resolution reason A parameter associated with a *discrepancy action* that provides a reason when a user closes a discrepancy.

response value The value that is assigned to a data point. This term usually refers to the fields in the Question area of a CRF.

response sequence The order in which the system expects data to proceed, from one field to the next. Also termed “Tab Order”, this is determined for each question during the CRF design of study setup. It is utilized when you use the Tab

key to navigate from one field to another.

S – T

save An action that commits pending data changes to the study database. In PDF mode, all save actions is explicit, initiated by the user clicking the Save button or choosing to save pending changes through the save edits / exit window.

save complete A save action that causes RDC to assign the CRF to the entry complete data entry status.

save incomplete A save action that causes RDC to assign the CRF to the *entry started* data entry status.

site A clinical location that participates within a given study.

time point A significant even in the history of a CRF. Used as criterion when viewing the Audit Trail tab. Examples of time points include:

- creation date
- verification dates
- approval dates

timestamp A value assigned to a data point that provides a chronology for significant events during a study. Such events include: the date / time when a value was created, the date / time when a value was updated, etc.

U

univariate discrepancy A *discrepancy* that is dependent on the value of a single *data point*. This type of discrepancy is usually when the value recorded for a response does not meet certain criteria that have been deemed acceptable by the PI, protocol, or study sponsor.

unplanned A designation attributed to any event or CRF that was not part of the protocol schedule or which occurs at a time other than was originally specified in the protocol schedule.

unplanned CRF A CRF collected at a visit at which it was not planned, that is, it is not part of the casebook.

update A process or condition in which CRF data or information, which has previously been saved is changed. A *privilege* that allows a user to initiate data entry, update data, initiate discrepancies, and update discrepancies.

user role A database role that is granted to a user or user group. There are five default user roles, however, any given study database may include some or all of these, and may include protocol-defined roles. RDC allows privileges to be assigned independently of user role assignment.

V

validation An action that entails the initiation and processing of sponsor-defined procedures, in the case of multiple data points, or edit checks, in the case of a single data point, that analyze collected data and return a query, or discrepancy, for each data point that does not meet the criteria defined in the procedure. Such a data-generated discrepancy is also referred to as a *validation error*.

validation error A condition associated with one or more data points that indicate the value

does not meet the criteria defined in a question definition or validation procedure. It is equivalent to a data-generated *discrepancy*.

value When used in the context of criteria and parameters, the choice that you assign to a parameter, which was chosen from a list of possible values.

visit A clinical even, which generally denotes the occurrence of a meeting between a patient and clinical staff at a study site. In the course of a visit, data related to the study is collected, which at some point is recorded and saved to the study database.

In RDC Onsite, a visit consists of one or more CRFs. By default, the system displays Spreadsheet Visit view in the Casebook Page, which displays, for the current patient list, all of the CRFs collected for a single visit.